ORDER

9120.1

ANTI-DRUG PROGRAM COMPLIANCE INSPECTOR ORDER

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DEPARTMENT OF TRANSPORTATION
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FOREWORD

This Order has been prepared by the Federal Aviation Administration (FAA) Office of Aviation Medicine, Drug Abatement Division. The primary purpose of the Order is to serve as a guide for FAA personnel when inspecting the anti-drug programs of covered aviation industry employers for compliance with the provisions of 49 CFR Part 40 and 14 CFR Parts 61, 63, 65, 67, 121, and 135.

Because the nature of the inspection process is dynamic, some procedures may change and/or expand over time. FAA inspection team members are not strictly limited to those activities described herein. Inspection procedures will be revised whenever substantial changes in regulations or inspection technique require it. Persons using this order should check carefully to ensure that the version they are using is the most current. The FAA invites constructive comments and suggestions from persons using the order. Input should be submitted in writing to:

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FEDERAL AVIATION ADMINISTRATION
ANTI-DRUG PROGRAM
COMPLIANCE INSPECTOR ORDER

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CHAPTER 1. GENERAL INFORMATION

SECTION 1. GENERAL

1. PURPOSE. This order documents the procedures used by Federal Aviation Administration (FAA) inspectors to assess the compliance of covered aviation industry employers with the anti-drug program requirements of 49 CFR Part 40, "Procedures for Transportation Workplace Drug Testing Programs," and 14 CFR Parts 61, 63, 65, 67, 121, and 135, "Anti-Drug Program for Personnel Engaged in Specified Aviation Activities." These procedures were developed to ensure that inspections are conducted accurately, fairly, and consistently throughout all FAA regions and are to be used in conjunction with guidance provided in Order 2150.3A, Compliance and Enforcement Program.

2. DISTRIBUTION. This order is distributed to all Medical Divisions in Washington headquarters and Regions.

3. BACKGROUND. On November 21, 1988, the FAA issued a final rule, 14 CFR Part 61, et al., requiring specified aviation employers and operators to submit for approval, and subsequently implement, anti-drug programs for those personnel who perform sensitive safety- and security-related functions. These regulations, as amended, together with Department of Transportation (DOT) regulation 49 CFR Part 40, form the basis for implementation of the aviation industry anti-drug program. Order 2150.3A provides guidance to FAA inspectors for industry compliance with anti-drug regulations and taking necessary enforcement actions.

a. FAA has the responsibility for ensuring that the aviation industry implements and complies with anti-drug regulations 14 CFR Part 61, et al., and 49 CFR Part 40. To fulfill this responsibility, the FAA has established a compliance inspection program that provides for inspections of all aspects of employers' anti-drug programs and assesses conformance with the regulations. This order contains the procedures used to conduct such inspections.

b. The inspections that will be conducted using this order are in execution of the Administrator's statutory plenary and specific authority, under the Federal Aviation Act of 1958, to ensure that aviation safety is maintained and that the regulations promulgated in accordance with that mandate are enforced. As the Administrator's representatives, inspectors may review all records and procedures necessary to adequately ensure compliance with DOT and FAA anti-drug regulations.

4. OBJECTIVE OF THE INSPECTION PROCESS. The objective of the industry anti-drug program compliance inspection process is to ensure aviation industry conformance with Federal anti-drug regulations. The results of each inspection must fairly and accurately

represent the status of the program being inspected. This goal will be achieved by establishing and following inspection procedures which are in accordance with Federal regulations and Order 2150.3A. The procedures contained in this handbook are designed to ensure completeness, consistency, and accuracy throughout the inspection process. Inspections will be conducted in a constructive atmosphere, in which emphasis is placed on improving the operation of the aviation industry's anti-drug programs as necessary to bring them into compliance with the intent of the regulations. The FAA will offer guidance to employers wherever possible to maintain effective programs that meet all requirements of the regulations.

5. COVERED ENTITIES, CONSORTIA AND CONTRACTORS.

a. Covered Entities. The FAA anti-drug regulations and the compliance inspection program apply to domestic and supplemental air carriers, commercial operators of large aircraft, air taxi and commuter operators, certain commercial operators, certain contractors to these air carriers and operators, and air traffic control facilities not operated by or under contract with the FAA or the U.S. Military.

b. Consortia. Under the FAA regulation, aviation employers and contractors may join consortia to provide for some of the activities required under the rule. Most of the consortia approved by the FAA are business entities that have been developed to capitalize on the market for services created by the anti-drug rule. While these businesses have greatly facilitated the implementation of the rule by a significant number of employers and contractors, they pose a special problem for compliance monitoring and enforcement.

(1) Covered employers are not relieved of responsibility for complying with the rule simply by virtue of the fact that they have joined a consortium. Consortium members must be inspected, and the key aspects of their programs reviewed, in the same manner as employers that operate their own programs. The only differences are that the collection company, MRO, laboratory, etc., have contracted with the consortium rather than the employer and that the consortium usually runs the random testing program for its members. It is the employer's responsibility to maintain the requisite records and to provide continued oversight to ensure that the consortium with which it has contracted is conducting its operations in accordance with the DOT and FAA anti-drug regulations.

(2) If a consortium has not implemented its program in accordance with its approved plan and the regulations, and its member employers are therefore not in compliance, the FAA's sanction authority applies to the employers. The consortium, however, is subject to disapproval of its program if the FAA determines that the consortium has failed to appropriately implement the plan that was approved by the FAA.

(3) In inspecting a consortium member, therefore, the inspectors must carefully evaluate the program in accordance with the guidance provided in this order, and must further determine in any identified area of non-compliance whether the non-compliance was caused by the employer or by the consortium. Again, while the fact that a failure was caused by the consortium does not relieve the employer of responsibility for complying with the rule, it may mitigate the degree of liability (if, for example, the employer took or attempted to take reasonable steps to monitor the consortium and cure any identified problems) and can affect the approval status of the consortium's plan.

c. Contractors. Employers covered by the anti-drug rule are responsible for ensuring that any contractor's employees who perform covered functions are in an FAA-approved anti-drug program. During the inspections conducted by the FAA, the review of contractors will largely be limited to determining whether and how the employer has ensured that its contractors' employees are appropriately covered. If, however, the contractor has submitted an anti-drug plan directly to the FAA, the contractor is responsible for implementing its program in accordance with FAA regulations and its approved plan. Should the FAA determine that the contractor is not in compliance with the regulations, the FAA has the authority to subsequently disapprove the program.

6. ORGANIZATION OF THE INSPECTOR ORDER.

a. Chapters 1, 2, 3, and 4 contain a general description of the anti-drug program compliance inspection process, the background and objective of the inspection process, the types of field activities conducted, and the organization and assignment of responsibilities needed to carry out the process. They also address inspection scheduling, planning, conduct in the field, and reporting and followup activities.

b. Chapter 5 contains checklists, forms, and data collection guidance. It is a "quick reference" guide for the inspector for planning, conducting, and following up each inspection.

c. Appendices 1 through 6 provide individual inspection procedures and checklists and regulatory references for inspector use. Appendices 2 through 6 correspond to the five topic areas (see Chapter 4, Section 5 for a list of topic areas) comprising the prescribed FAA anti-drug program, and contain detailed instructions for reviewing each topic, together with checklists of inspection elements.

7. AUTHORITY TO CHANGE THIS DOCUMENT. The Office of Aviation Medicine is responsible for all changes to this order and its appendices. Regional supplements to this order are prohibited.

8. ACRONYMS. A listing of acronyms is provided in this order for clarification.

a.	ADAP	Aviation Drug Abatement Program Manager
b.	CEDMS	Compliance and Enforcement Data Management System
c.	CFR	Code of Federal Regulations
d.	DHHS	Department of Health and Human Services
e.	DOT	Department of Transportation
f.	EAP	Employee Assistance Program
g.	EIR	Enforcement Investigative Report
h.	EIS	Enforcement Information Subsystem
i.	FAA	Federal Aviation Administration
j.	FAR	Federal Aviation Regulations
k.	MRO	Medical Review Officer
l.	NIDA	National Institute on Drug Abuse
m.	NTSB	National Transportation Safety Board
n.	POC	Point of Contact

9.-10. RESERVED.

CHAPTER 2. TYPES OF COMPLIANCE INSPECTION ACTIVITIES

SECTION 1. INSPECTIONS

11. GENERAL. FAA inspectors may employ a variety of inspection activities to ensure compliance with the anti-drug regulations. These activities range from comprehensive, announced full scope inspections, which are scheduled in advance and address all aspects of an employer's program, to limited and narrowly focused investigations of specific aspects of anti-drug program implementation, to unannounced inspections.

12. COMPREHENSIVE INSPECTIONS. Comprehensive, announced inspections, which comprise the bulk of the compliance inspection program, are thorough reviews of all aspects of employers' anti-drug programs. Although attention may sometimes focus on specific areas based on information concerning potential problems, the overall format of such inspections is standardized in accordance with this order. Each employer to be inspected is apprised of the date of the inspection, and the schedules are updated quarterly. In some cases, inspections may be conducted without advance notice to the employer. The need for such inspections is determined by FAA headquarters, with input from the regional offices.

13. LIMITED SCOPE INSPECTIONS. Under certain circumstances, inspections of limited scope may be conducted in response to a specific problem. Problems may be identified from any of a variety of information sources, including analyses of prior inspection results and semiannual/annual reports, individual or union complaints, or other means. For example, FAA headquarters may receive complaints concerning improper collection procedures. In that case, an inspection focusing on the employer's collection procedures may be conducted. Limited-scope inspections may focus on a single employer or entity, as in the example above, or a representative group of employers if information indicates that a problem is widespread.

SECTION 2. INVESTIGATIONS

14. GENERAL. During the course of an inspection, or whenever there is a need to verify the facts and circumstances surrounding a suspected issue of non-compliance with regulatory requirements, an investigation may be conducted. The purpose of an investigation is to gather facts to determine whether an item of non-compliance exists and whether imposition of civil penalties or other sanctions is warranted for an employer that is not in compliance with the regulations. Investigations are conducted in accordance with the procedures contained in Order 2150.3A and are usually conducted by, or at the direction of, FAA headquarters. The actual investigatory work may be performed by headquarters personnel, regional staff, or both.

15.-20. RESERVED.

CHAPTER 3. PROGRAM ORGANIZATION AND RESPONSIBILITIES

SECTION 1. ORGANIZATION

21. POLICY. The FAA industry anti-drug program compliance inspection program is directed by FAA headquarters Compliance and Enforcement Branch which:

a. Oversees and guides activities to ensure achievement of overall program objectives

b. Formulates policy and procedures for compliance monitoring

c. Evaluates the compliance program to determine operational effectiveness

d. Develops required training programs and improved inspection procedures

e. Analyzes inspection results and industry statistical summary reports.

f. The FAA headquarters Compliance and Enforcement Branch will maintain a staff of trained compliance inspectors who are responsible for ensuring the proper conduct of inspections and investigations with respect to aviation employers' anti-drug programs. Each FAA region maintains a staff of trained compliance inspectors to conduct inspections and investigations.

g. The number of personnel assigned to a specific inspection trip will depend on the size and number of employers scheduled to be inspected during the trip. Each team is headed by an inspection team leader. In cases where an employer's anti-drug program crosses FAA regional boundaries, the inspection team leader will coordinate efforts with other regions to extend the inspection to other employer sites if there are indications that the problems encountered during the initial inspection of the employer are serious and may exist at the employer's other sites as well. A region may be assigned responsibility for coordinating inspection activities and results for large employers that are headquartered in the region but have sizeable operations located in other regions.

22.-24. RESERVED.

SECTION 2. RESPONSIBILITIES

25. GENERAL. This section outlines the responsibilities of FAA headquarters and the regional offices for planning, conducting, and reporting the results of compliance inspections and investigations. It also summarizes the responsibilities of the inspection teams; these are more fully discussed in Chapter 4.

26. FAA HEADQUARTERS COMPLIANCE AND ENFORCEMENT BRANCH. The FAA headquarters office is responsible for formulating and implementing the aviation anti-drug compliance inspection program. Its primary responsibility is to oversee inspection program activities to ensure achievement of program objectives. Responsibilities include:

a. Developing policy and procedures for compliance inspections

b. Establishing and conducting training programs for inspectors

c. Developing criteria for inspection selections

d. Approving inspection and investigation schedules

e. Arranging for personnel to augment inspection teams, when required

f. Reviewing and approving Enforcement Investigative Reports (EIRs)

g. Maintaining the anti-drug program Compliance and Enforcement Data Management System (CEDMS)

h. Maintaining a comprehensive tracking system for inspection statistics

i. Overseeing the effectiveness of followup programs for employer deficiencies

j. Conducting quarterly reviews of the compliance inspection program

k. Developing enhanced inspection procedures

l. Ensuring consistency of inspections

27. FAA REGIONS. Each FAA region is responsible for performing its assigned operational aspects of the compliance inspection program. Responsibilities include:

a. Planning and conducting field inspections

b. Planning and conducting investigations

c. Meeting with industry anti-drug program representatives

d. Preparing all enforcement correspondence (Warning Notices, Letters of Correction, Letters of Investigation, EIRs, or other enforcement action documentation as required)

e. Maintaining the regional tracking system for inspection results.

f. Meeting minimum training requirements

g. Planning and managing program budget

28. INSPECTION TEAMS. The inspection teams are responsible for planning, conducting, and reporting inspections. They also:

a. Provide input to the regional and headquarters scheduling process

b. Plan and coordinate the conduct of inspections with employers

c. Conduct field inspection and investigation activities, as assigned

d. Generate results of inspections in accordance with FAA Order 2150.3A

e. Conduct assigned inspection followup activities

CHAPTER 4. CONDUCTING THE INSPECTIONS

SECTION 1. OVERVIEW

35. GENERAL. The successful conduct of anti-drug program inspections entails accomplishing a sequence of five interrelated activities. This sequence begins with inspection scheduling; proceeds through detailed planning, completion of on-site inspection activities, and reporting of inspection results; and concludes with post-inspection followup activities.

SECTION 2. ROLE OF THE INSPECTION TEAM LEADER

36. GENERAL. The assigned team leader for each inspection plays a critical role in accomplishing the goals of the compliance program. This individual provides input to the scheduling process and is directly responsible for assuring that all critical aspects of inspection planning, conduct, and reporting are accomplished according to established procedures. Inspection guides to assist with this process are contained in Chapter 5. The team leader is selected by either headquarters or the regions to assemble an inspection team and coordinate team inspection activities. Table 1 summarizes the team leaders key functions, which are further described in the following sections.

a. For announced inspections confirm in writing the date and time of the inspection with the employer, discuss logistical arrangements, and request documentation no later than four weeks prior to inspection (unless no-notice); follow up to ensure documentation is received no later than two weeks prior to inspection

b. Obtain from FAA files copies of employer's approved anti-drug plan, semiannual and annual reports for the previous two years, and the results of the two most recent inspections, if available

c. Review documentation to ensure that all is present and indicate to the team any areas which may require special attention during the inspection

d. Provide documentation to the team for review no later than one week prior to the inspection

f. Notify region or headquarters, as appropriate, if additional personnel are needed to staff the inspection team

g. Assign areas of inspection responsibility to team members

h. Ensure that travel and lodging arrangements have been made no later than one week prior to the inspection

i. Oversee and coordinate inspection team members' activities to maximize efficiency and comply with overall objectives of the inspection process during the field activities portion of inspections

j. Conduct inbriefing, team review, and outbriefing meetings

k. Ensure that evidence to support items of non-compliance is thoroughly documented

l. Ensure that sufficient information is gathered, verified, and documented during the inspection to support development of Warning Notices, Letters of Correction, Letters of Investigation, EIRs or other enforcement action, as appropriate, in accordance with Order 2150.3A

m. Assign responsibility for documenting inspection results to team members and review to ensure high quality

n. Forward draft inspection results and any enforcement action documentation to regional Drug Abatement Program Manager for final review and approval

o. Enter information on items of non-compliance into regional tracking system and CEDMS, as appropriate

p. Follow up on status of corrective actions.

q. Notify regional Drug Abatement Program Manager when corrective actions have not been completed as required

r. Ensure completion of corrective actions.

37.-42. RESERVED.

SECTION 3. SCHEDULING

43. GENERAL. The eventual goal of the compliance inspection program is to inspect every employer with an anti-drug program. FAA headquarters provides quarterly scheduling guidance to the regions. The number of inspections required by this guidance reflects available inspection staff and the number, size, and past performance of employers within the regions. Inspection schedules are flexible and subject to revision to accommodate

unanticipated demands on regional inspection staff, such as targeted inspections or investigations. Inspections and investigations also may be scheduled on an unannounced basis by FAA headquarters, based on information received from the industry, employer semiannual and annual reports, data from previous inspection reports, and other sources that will be identified with non-compliance issues.

44.-48. RESERVED.

SECTION 4. PLANNING

49. GENERAL. The inspection team leader has primary responsibility for planning inspection trips. For announced inspections, he/she selects the team members for the inspection trip, contacts the employer(s) scheduled to be inspected and confirms the inspection dates in writing, discusses on-site logistical requirements, and requests any documentation needed by the team to plan the inspection, usually no later than four weeks prior to the inspection trip. The on-site logistical requirements of the team include a private area with adequate work space and telephones, and access to a copy machine. The documentation to be requested from each employer is listed in Table 2. The employer generally is asked to assemble the documentation and forward it to the team leader within two weeks of the request. The team leader follows up to ensure that it is received on time and that it is complete. He/she also obtains FAA file copies of the employer's approved anti-drug program plan, semiannual and annual reports for the previous two years, and the results of the previous two inspections, if available. In the case of no-notice or unannounced inspections, only that documentation available without contacting the employer is used to plan the inspection.

a. The team leader reviews the documentation, determines whether there are any specific areas requiring special attention during the inspection, and passes that information on to the team members, along with the documents for their review. No later than one week prior to the inspection trip, the team leader ensures that the team's travel and lodging arrangements have been made and that logistical arrangements have been completed by each employer.

b. Employer documents request list for inspection planning.

(1) Contracts with collection sites, laboratories, medical review officer (MRO), and employee assistance program (EAP) service provider, if applicable

(2) Consortium agreement(s), if applicable (other than consortia plans on file with FAA)

(3) Internal policies and procedures for the anti-drug program

(4) A sample of the drug testing custody and control form in use

(5) Written instructions provided to specimen collectors

(6) The number of blind performance test specimens submitted during the previous 12 months and a summary of the results

(7) A summary of reportable accidents, as defined in the Federal Aviation Regulations (FAR), which occurred during the previous 12 months

(8) Completed Points of Contact (POC) form and Document/Record Custodians and Repository Locations form

(9) Maps (if available), showing locations of facilities to be visited during inspection.

SECTION 5. FIELD ACTIVITIES

50. GENERAL.

a. This section contains general guidance for conducting compliance inspection program field activities. Anti-drug programs are divided into five topic areas to organize the compliance inspection process and assign specific inspection tasks to team personnel. These topics are:

(1) Employer Administrative and Quality Assurance Activities

(2) Specimen Collection

(3) Medical Review Officer Activities

(4) Employee Assistance Programs

(5) Recordkeeping and Reporting.

b. The team leader assigns responsibility for one or more of the five topics to specific team members during the planning phase. These team members are responsible for conducting the review of their assigned area(s). Specific, detailed procedures and checklists for inspecting each of the above topics are contained in Appendices 2 through 6 of this order.

c. Team members gather information to perform the inspection in their assigned topics through five general methods:

(1) Reviewing documentation

(2) Interviewing key personnel

(3) Observing actual procedures

(4) Examining equipment and facilities

(5) Conducting limited performance testing of individuals' knowledge of policies and procedures.

d. The inspections do not include detailed quality assurance checks of laboratories, but rely primarily on reviewing employer documentation to assess compliance. If the team discovers any instances of verified or suspected laboratory non-compliance with regulations, it notifies FAA headquarters, which may choose to conduct followup interviews or targeted inspections, or may notify the certifying agency to evaluate the laboratory's compliance with regulatory requirements. On-site evaluation of a collection site and the Medical Review Officer (MRO) activity is conducted for each inspected employer.

e. Reviewing records is an important part of the inspection process. Inspectors randomly select a representative sample of records for review. The results of record reviews should be adequately documented to establish compliance or non-compliance, and photocopies of records should be made as needed to support suspected areas of non-compliance.

f. Case studies of verified positive drug tests are another important inspection technique by which the inspection team can evaluate how well the various areas of the drug testing program perform as a whole. In a case study, a small sample of records of employees who received verified positive drug test results is randomly selected and reviewed to determine whether the complete testing process from start to finish (e.g., selection, specimen collection, chain of custody, laboratory testing, MRO, employer notification) was performed in accordance with the regulations. The case study may also include, where applicable, determining whether the employees passed drug tests prior to being hired or returned to duty in covered positions, whether employees who return to duty after having failed or refused a drug test are subject to unannounced testing for a period determined by the MRO but not exceeding 60 months, and, in the case of employees who hold Part 67 medical certificates, whether the MRO made a determination of probable drug dependence or non-dependence and subsequently made the notifications specified in the regulations.

g. Inspectors look for and may report on noteworthy practices as well as deficiencies. The headquarters office may collect and periodically disseminate information to aviation industry employers on common problems and successful solutions to improve the anti-drug program.

h. The inbriefing and outbriefing meeting with the employer's representatives are important aspects of the inspection process. The inbriefing sets the tone for the inspection and allows for the introduction of all parties involved. The outbriefing is held at the end of the inspection to notify the employer of the facts collected by the team and, if necessary, to resolve any differences between the inspectors' and the employer's understanding of such facts. The purpose of the meeting is not to obtain the employer's concurrence with the inspection results, but rather to identify and advise the employer as to factual discrepancies.

Possible sanctions the FAA may impose as a result of any non-compliance reported by the inspection team will not be discussed. The team leader conducts this outbriefing to discuss areas of non-compliance and this meeting should be attended by all inspection team members and any representatives the employer desires to have attend. The team ensures that pertinent observations, which may include exemplary practices observed, are discussed with the appropriate employer representatives during this outbriefing meeting. A schedule for the employer's completion of any required corrective action should also be agreed upon during the outbriefing.

51.-60. RESERVED.

SECTION 6. INSPECTION AND INVESTIGATION TECHNIQUES

61. GENERAL. The overall goal of an inspection is to determine employer compliance with DOT and FAA anti-drug regulations. The inspectors' objective is to obtain defensible evidence to establish whether or not compliance has been achieved. Such evidence includes all forms of information by which any fact pertaining to compliance tends to be established or disproven.

62. METHODS OF OBTAINING EVIDENCE.

a. Methods for obtaining evidence include direct observation, interviews of persons, review of pertinent documents, and examination of physical evidence.

b. The preferred method of verification of compliance is through direct observation, which should be documented in writing as promptly as possible. All observations that support a determination of non-compliance should be thoroughly documented,

including the date, time, location, persons present, and activity at the time of the observation.

c. In some instances, it may not be possible to personally observe compliance. Reliance upon interviews with witnesses or directly involved persons is then required. Where a formal investigation of suspected non-compliance is involved, the documentation of witness testimony is often crucial. In selecting and interviewing witnesses, inspectors should adhere to the guidance in Order 2150.3A. Some key points to remember are that witnesses should be selected based on their knowledge and competence concerning the information sought, multiple witnesses should be interviewed, if possible; and testimony should be reduced to writing, either by the witness or the inspector, and signed by the witness. An example witness statement form is provided in Chapter 5. Witnesses should be informed that the provision of evidence is not done under oath as in a court proceeding but that detailing the precise facts serves everybody's best interests. In many circumstances, such information may be used to prove non-compliance and can be helpful in leading the inspector to other persons who have direct knowledge or documentation which supports a determination of non-compliance. When conducting interviews, it is useful to remember the following general guidelines:

(1) Plan the interview in advance

(2) Put the interviewed person at ease

(3) Maintain control of the interview

(4) Ask direct and relevant questions

(5) Be attentive and listen

(6) Obtain a signed witness statement, if appropriate

(7) Refer to Order 2150.3A if there is any question concerning the proper conduct or documenting of the interview.

d. Documentary evidence is generally the most common type of evidence examined during an inspection or investigation. Documentation is valuable not only as direct evidence but as a means for cross-referencing and verifying physical observations and interview results. Thus, a significant portion of an inspection or investigation will normally be spent in reviewing documents and records. For announced inspections, it is useful to inform the

inspected employer of the types of records to which access will be required. In any case, the responsible inspector should promptly make provisions to obtain, review, retain, and/or copy records, as needed. A record should generally be made of the documents reviewed and the dates, times, and locations such reviews took place. Copies should be made of those documents used to establish non-compliance, in accordance with the guidance in Order 2150.3A, and the inspector should indicate when, where, and from whom such documents were obtained. All copies should be legible and accurate and marked in accordance with the certifying statement from Order 2150.3A shown in Chapter 5 of this order.

e. Physical evidence consists of objects or items, such as specimen collection materials, computer software programs, or other physical matter which can establish compliance or non-compliance. Care must be exercised so that handling of physical evidence does not result in damage, loss, or alteration, and chain of custody must be maintained for any item of physical evidence taken into the possession of an inspector.

f. In summary, the goal of the on-site inspection activity is to gather, document, protect, and report on any pertinent evidence, regardless of its form, that can be used to establish the state of compliance of the employer's anti-drug program in place at the time of the inspection. Careful attention to the guidance contained in Order 2150.3A will ensure proper and effective evidence gathering that results in a fair and impartial evaluation at the conclusion of the inspection.

63.-72. RESERVED.

SECTION 7. INSPECTION FOLLOWUP

73. RESULTS.

a. The inspection results are documented following the inspection. These written results should document, at a minimum, any compliance issues noted for each of the five topic areas examined during the inspection or investigation. Items of non-compliance, noteworthy practices, and any other items of interest should be noted. Problem areas observed in the inspected program that do not directly relate to specific regulatory requirements may also be noted as items of concern.

b. Inspection results are documented in the following ways:

(1) Completed automated inspection checklists

(2) Inspector field notes

(3) Copies of employer documents

(4) Witness statements

(5) Appropriate administrative or legal enforcement actions as prescribed in Order 2150.3A

(6) Completed EIR's.

c. In conjunction with documenting inspection results, the team leader ensures that any resulting enforcement action information is properly documented in accordance with Order 2150.3A.

d. The team leader has overall responsibility for ensuring that inspection results are fully documented and completed on time. Headquarters reviews the draft inspection results and any enforcement action documentation, returning those that require revisions to the regional Drug Abatement Program Manager. In order to ensure consistency of enforcement actions, Headquarters approves the final versions of the inspection results and enforcement documents.

74.-79. RESERVED.

SECTION 8. INSPECTION ENFORCEMENT ACTIVITIES

80. GENERAL. The proper selection and application of enforcement actions are address in Order 2150.3A. Upon completion of an inspection or investigation, any required enforcement actions are taken in accordance with Order 2150.3A and the status of non-compliance issues and corrective actions are monitored and followed up, as appropriate.

a. If items of non-compliance have been noted, enforcement action may be required to ensure that appropriate and timely corrective action is taken. The FAA headquarters office has the overall responsibility for coordinating and approving enforcement actions. These actions may take one of several forms as described in 2150.3A: administrative action or legal enforcement action which includes civil and criminal penalties and certificate action. One of these types of enforcement actions may be selected based on the severity or degree of non-compliance observed. Administrative action is typically employed in instances of non-compliance where there is no significant impact on safety or obvious lack of competence,

and when the violation was not deliberate or indicative of a pattern of similar non-compliance. Legal enforcement, on the other hand, is appropriate when serious safety issues are involved or there is a pattern of non-compliance which indicates an inability or unwillingness to comply with regulatory requirements.

b. The FAA Compliance and Enforcement Branch has created the Compliance and Enforcement Data Management System (CEDMS) for tracking all compliance and enforcement activities concerning aviation entities covered by the DOT and FAA anti-drug regulations. This database is used by all inspectors to store and track all compliance and enforcement information, including all actions initiated by both the FAA and the aviation industry. In addition, this system will be used to produce a variety of reports on demand.

c. CEDMS is not to be confused with the Enforcement Information Subsystem (EIS), which is the agency-wide subsystem for all Enforcement Investigative Reports (EIR).

81.-90. RESERVED.

CHAPTER 5. INSPECTION FORMS AND GUIDELINES

91. GENERAL. This chapter of the order contains guidance useful to the inspection team leader and team members in efficiently planning and organizing all required inspection activities. It includes checklists for the planning, conduct and followup of all inspections. It also provides sample formats for letters notifying employers and consortia of upcoming inspections and identifies the actions required of these entities to prepare for an inspection. Guidance concerning the evaluation of random selection techniques is also provided. Finally, a number of useful inspection aids and forms are included for use in documenting inspection activities.

92. GENERAL. The FAA Team Leader Guide (Figure 5-1) is used by the team leader to organize and conduct the inspection. This is a general guide to assist the team leader in identifying the documents to be obtained from the employer, arrangements to be made prior to the inspection, and items to keep in mind when conducting the inspection. It also includes a post-inspection guide used to wrap up and close an inspection and an inspection inbriefing/outbriefing guide.

93.-96. RESERVED.

FIGURE 5-1. FAA TEAM LEADER GUIDE

Pre-Inspection

__ Send notification letter with enclosures to request documentation from the employer

__ Employer/Consortium Inspection Guide
- __ Inspection Schedule
- __ Documents to be sent to FAA
- __ Points of Contact Form
- __ Document/Record Custodians and Repository Locations Form

__ Confirm date of announced inspection with employer

__ Discuss logistical arrangements with employer

__ Obtain maps if available
__ Copier
__ Team meeting room
__ Private room

__ Follow up to ensure documentation is received

__ Obtain documents needed from FAA files

__ Review documentation for completeness and special needs areas

__ Provide documentation to the team for review

__ Notify region or headquarters if additional personnel are needed

__ Ensure travel and lodging arrangements have been made for entire team

__ Complete inspection schedule assigning areas of responsibility for team members

Inspection

__ Conduct initial team meeting

__ Coordinate inspection team members' activities to maximize efficiency during the field activities portion of the inspection

__ Conduct inbriefing (see attached inbriefing guide)

__ Conduct review meetings with team members during inspection and prior to outbriefing

__ Ensure that sufficient information is gathered, verified, and documented during the inspection to support development of administrative or legal enforcement action, as appropriate, and required by Order 2150.3A

__ Conduct outbriefing (see attached outbriefing guide)

Post-Inspection

__ Assign responsibility for after action report writing to team members and review report to ensure accuracy and quality

__ Forward documentation to region or headquarters, as appropriate, for final review and approval

__ Enter items of non-compliance in Compliance and Enforcement Data Management System (CEDMS)

__ Send formal correspondence required by Order 2150.3A, if required

__ Follow up on status of corrective actions and update CEDMS tracking system

__ Notify regional or headquarters office, as appropriate, when corrective actions have not been completed as required

__ Acknowledge completion of corrective actions.

FIGURE 5-2. DOCUMENTS TO BE OBTAINED BY THE FAA TEAM LEADER FROM THE EMPLOYER

1/	_____	Contracts with collection site(s), laboratory(s), MRO(s), and EAP service provider, if applicable
	_____	Consortium agreement(s), if applicable (other than consortia plans on file with FAA)
	_____	Internal policies and procedures for the anti-drug program
	_____	A sample drug testing custody and control form
	_____	Written instructions provided to specimen collectors
	_____	The number of blind performance test specimens submitted during the previous 12 months and results, if applicable
	_____	A summary of reportable accidents, as defined in the Federal Aviation Regulations (FAR), which occurred during the previous 12 months
	_____	Completed POC form and Document/Record Custodians and Repository Locations form
	_____	Maps (if available), with locations, for areas outside the office being used for the inspection.

Team Leader's Address Here

1/ These documents do not need to be sent to the FAA, but they must be available at the inspection site for FAA review at the time of the inspection

FIGURE 5-3. FAA TEAM LEADER INSPECTION INBRIEFING/OUTBRIEFING GUIDE

Inbriefing

_____ Introduce team members to employer representatives

_____ Explain the general purpose and scope of the inspection

_____ Review the inspection schedule

_____ Confirm employer points of contact (POCs) and document/ record locations

_____ Describe the nature of the outbriefing to be held at the end of the inspection.

Outbriefing

_____ Thank employer for cooperation and assistance, as appropriate

_____ Request employer hold questions and comments till end of briefing

_____ Review general scope of inspection and activities conducted and state there will be a written follow-up to the inspection.

_____ State non-compliance items.

_____ Highlight key (major) areas of concern, if any

_____ Identify noteworthy practices observed, if any

_____ Negotiate with employer for a time limit for completing corrective actions.

_____ Describe headquarters review process

_____ Do not leave written inspection materials or results with employer.

Section 2. Sample Employer Notification Letter

97. EMPLOYER NOTIFICATION LETTER. Figure 5-4, Sample Employer Notification Letter and enclosures which provide a standard format for use by the inspection team leader in notifying employers of upcoming inspections. The enclosures provide guidance to the inspected employer in assembling needed information and documents. This letter and enclosures should be received by the employer in a reasonable time prior to the inspection so that requested documents can be furnished to the team for review in preparing for the on-site inspection.

a. The inspection schedule in Figure 2 should be completed by the team leader and forwarded with the notification letter so that the employer can arrange to have key personnel available for discussions with the team.

b. Figures 3, 4, and 5 are to be completed and returned by the employer to the FAA team leader, together with any schedule conflicts the employer may have noted. Also, the employer should indicate on the schedule the employer representatives who will be participating in the activities noted on the schedule.

FIGURE 5-4. SAMPLE EMPLOYER NOTIFICATION LETTER

MR. JOHN DOE, PRESIDENT
EMPLOYER NAME
ADDRESS
CITY, STATE ZIP CODE

Dear Mr. Doe:

This letter is to inform you that the Federal Aviation Administration's (FAA) Compliance and Enforcement Branch will conduct an inspection of **(EMPLOYER NAME)** 's anti-drug program on **(DATE)**. A **(NUMBER)** member inspection team under the direction of **(NAME)**, FAA Team Leader, will conduct the inspection. The inspection will begin at **(TIME)** on **(DATE)** and end at approximately **(TIME)** on **(DATE)**.

The purpose of this inspection is to determine that **(EMPLOYER NAME)** has implemented its anti-drug program in accordance with 49 CFR Part 40 and 14 CFR Part 61, et al.

To facilitate the inspection, the following documentation is provided:

- Enclosure 1: Employer Inspection Guide
- Enclosure 2: Inspection Schedule
- Enclosure 3: Documents to be sent to the FAA
- Enclosure 4: Points of Contact (POC) Form
- Enclosure 5: Document/Record Custodians and Repository Locations.

Enclosure 1 is a guide to assist you in preparing for the inspection. Enclosure 2 is a sample inspection schedule.

We ask that you forward the documents requested in Enclosure 3 and the completed Enclosures 4 and 5, no later than **(DATE)** to: **(TEAM LEADER'S ADDRESS)**.

Should you have any questions concerning this inspection, please contact **(TEAM LEADER)** at **(PHONE NUMBER)**.

Sincerely,

(REGIONAL DRUG ABATEMENT PROGRAM MANAGER)

Enclosures
cc: (Employer Anti-Drug Program Manager)

FIGURE 5-5. ENCLOSURE 1 - EMPLOYER INSPECTION GUIDE

_____ Confirm dates of scheduled inspection with FAA

_____ Send requested documentation not less than four weeks before the inspection, if possible:

___ Documents to be sent to the FAA

___ Points of Contact form

___ Document/Record Custodians and Repository Locations form

_____ Eliminate scheduling conflicts before the inspection

_____ Ensure that appropriate management representatives will be available to discuss:

- Employer Administrative and Quality Assurance Activities
- EAP Training
- Specimen Collection
- Recordkeeping and Reporting
- MRO Services
- Laboratory Services
- Random Selection

_____ Provide for logistics requirements of the FAA

___ Copier

___ Team Meeting Room

___ Points of Contact

_____ Ensure relevant documents will be readily available

_____ Attend inbriefing and outbriefing with FAA inspection staff

FIGURE 5-6. ENCLOSURE 2 - SAMPLE AVIATION EMPLOYER INSPECTION SCHEDULE

Day 1
(Day and Date)

FAA TEAM LEADER:
PHONE NO. _____

EMPLOYER POC:
PHONE NO. _____

Time	Activity	FAA Staff	Employer Staff
8:30 - 9:00 a.m.	• Inbriefing	Lead:	(As Appropriate)
9:00 - 11:00 a.m.	• Administrative & Quality Assurance	Lead:	
11:00 - 12:00 p.m.	• EAP	Lead:	
12:00 - 1:00 p.m.	• Lunch		
1:30 - 2:30 p.m.	• Specimen Collection	Lead:	
2:30 - 5:00 p.m.	• Team Meeting	Lead:	N/A

FIGURE 5-6. (Cont'd)

Day 2
(Day and Date)

FAA TEAM LEADER:
PHONE NO. _____

EMPLOYER POC:
PHONE NO. _____

Time	Activity	FAA Staff	Employer Staff
12:00 - 1:00 p.m.	•Lunch		
1:30 - 2:30 p.m.	•MRO	Lead:	
2:30 - 5:00 p.m.	•Team Meeting	Lead:	N/A

Day 3
(Day and Date)

8:30 - 11:30 a.m.	•Followup Inspection Activity	Lead:	
11:30 - 12:30 p.m.	•Lunch		
1:00 - 3:00 p.m.	•Outbriefing	Lead:	

FIGURE 5-7. ENCLOSURE 3 - DOCUMENTS TO BE SENT TO THE FAA

[1/]	_____	Contracts with collection site(s), laboratory(s), medical review officer (MRO), and employee assistance program (EAP) service provider, if applicable
	_____	Consortium agreement(s), if applicable (other than plans on file with FAA)
	_____	Internal policies and procedures for the anti-drug program
	_____	A sample of the drug testing custody and control form in use
	_____	Written instructions provided to specimen collectors
	_____	The number of blind performance test specimens submitted during the previous 12 months and a summary of the results
	_____	A summary of reportable accidents, as defined in the Federal Aviation Regulations (FAR), which occurred during the previous 12 months
	_____	Completed Points of Contact form and Document/Record Custodians and Repository location form
	_____	Documents should be sent to the following address:

Team Leader's Address Here

[1/] These documents do not need to be sent to the FAA, but they must be available at the inspection site for FAA review at the time of the inspection.

FIGURE 5-8. ENCLOSURE 4 - FAA DRUG ABATEMENT COMPLIANCE INSPECTION POINTS OF CONTACT

Employer Name _____ **Date** _____

Inspection Topic	Point of Contact - Name/Title	Location/Address/ Phone No.
1. Employer Administrative and Quality Assurance Activities		
2. Specimen Collection Sites (use continuation sheet if needed) a. b. c.		
3. Medical Review Officer (use continuation sheet if needed)		
4. EAP		
5. Recordkeeping & Reporting		
6. Other (as appropriate)		

FIGURE 5-9. ENCLOSURE 5 - DOCUMENT/RECORD CUSTODIANS AND REPOSITORY LOCATIONS

In addition to the information/documents previously requested, please identify the custodian and his/her phone number and the repository locations for each of the items listed below.

Document/Record	Custodian Name	Custodian Telephone	Repository Location Building/Room/ Address
1. Individual Training Records			
2. Training Lesson Plans, Rosters, and Posters/Handouts/Aids			
3. Specimen Collection Logs			
4. Chain of Custody Forms			
5. Individual Drug Test Results			
6. MRO Determination Documentation and Part 67 Notifications to the Federal Air Surgeon			
7. Quality Assurance Blind Testing Results			
8. Random Selection Documentation			

FIGURE 5-9. (Cont'd)

Document/Record	Custodian Name	Custodian Telephone	Repository Location Building/Room/ Address
9. Documentation for Reasonable Cause and Post-Accident Tests			
10. Documents pertaining to drug testing arbitration or litigation			
11. Employee complaints concerning the anti-drug program			
12. Records of the Disposition of Positive Drug Test Cases			
13. MRO Correspondence			
14. Laboratory Correspondence (include monthly report on reportable statistical data)			
15. Documentation to verify contractor compliance			
16. Reportable Accident Records			

98. CONSORTIUM NOTIFICATION LETTER. This sample consortium notification letter and enclosures provide a standard format for use by the inspection team leader in notifying consortia of upcoming inspections. The enclosures provide guidance to the inspected consortium in assembling needed information and documents. This letter and enclosures should be received by the consortium four to six weeks prior to the inspection so that requested documents can be furnished to the team for review in preparing for the on-site inspection.

a. The inspection schedule in Figure 2 should be completed by the team leader and forwarded with the notification letter so that the consortium can arrange to have key personnel available for discussions with the team.

b. Figures 3, 4, and 5 are to be completed and returned by the consortium to the FAA team leader, together with notice of any schedule conflicts the employer may have identified. Also, the consortium should indicate on the schedule the consortium staff person(s) who will be participating in the activities noted on the schedule.

99.-104. RESERVED.

FIGURE 5-10. SAMPLE CONSORTIUM NOTIFICATION LETTER

MR. JOHN DOE, PRESIDENT
COMPANY NAME
ADDRESS
CITY, STATE ZIP CODE

Dear Mr. Doe:

This letter is to inform you that the Federal Aviation Administration's (FAA) Compliance and Enforcement Branch will conduct an inspection of **(COMPANY NAME)**'s anti-drug program on **(DATE)**. A **(NUMBER)** member inspection team under the direction of **(NAME)**, FAA Team Leader, will conduct the inspection. The inspection will begin at **(TIME)** on **(DATE)** and end at approximately **(TIME)** on **(DATE)**.

The purpose of this inspection is to determine that **(COMPANY NAME)** has implemented its anti-drug program in accordance with 49 CFR Part 40 and 14 CFR Part 61, et al.

To facilitate the inspection, the following documentation is provided:

- Enclosure 1: Consortium Inspection Guide
- Enclosure 2: Inspection Schedule
- Enclosure 3: Documents to be sent to the FAA
- Enclosure 4: Points of Contact (POC) Form
- Enclosure 5: Document/Record Custodians and Repository Locations.

Enclosure 1 is a guide to assist you in preparing for the inspection. Enclosure 2 is a sample inspection schedule.

We ask that you forward the documents requested in Enclosure 3 and the completed Enclosures 4 and 5, no later than **(DATE)** to: **(TEAM LEADER'S ADDRESS)**.

Should you have any questions concerning this inspection, please contact **(TEAM LEADER)** at **(PHONE NUMBER)**.

Sincerely,

(REGIONAL DRUG ABATEMENT PROGRAM MANAGER)

Enclosures
cc: (Company Anti-Drug Program Manager)

FIGURE 5-11. ENCLOSURE 1 - CONSORTIUM INSPECTION GUIDE

_____ Confirm dates of scheduled inspection with FAA

_____ Send requested documentation not less than four weeks before the inspection:

___ Documents to be sent to the FAA

___ Points of Contact form

___ Document/Record Custodians and Repository Locations form

_____ Eliminate scheduling conflicts before the inspection

_____ Ensure that appropriate management representatives will be available to discuss each of the following if provided as part of the consortium service:

- Administrative and Quality Assurance Activities
- EAP Training
- Specimen Collection
- Recordkeeping and Reporting
- MRO Services
- Laboratory Services
- Random Selection

_____ Provide for logistics requirements of the FAA

___ Copier

___ Team Meeting Room

___ Points of Contact

_____ Ensure relevant documents will be readily available

_____ Attend inbriefing and outbriefing with FAA inspection staff.

FIGURE 5-12. ENCLOSURE 2 - SAMPLE CONSORTIUM INSPECTION SCHEDULE

Day 1
(Day and Date)

FAA TEAM LEADER:
PHONE NO. _____

CONSORTIUM POC:
PHONE NO. _____

Time	Activity	FAA Staff	Employer Staff
8:30 - 9:00 a.m.	• Inbriefing	Lead:	(As Appropriate)
9:00 - 11:00 a.m.	• Administrative & Quality Assurance	Lead:	
11:00 - 12:00 p.m.	• EAP	Lead:	
12:00 - 1:00 p.m.	• Lunch		
1:30 - 2:30 p.m.	• Specimen Collection	Lead:	
2:30 - 5:00 p.m.	• Team Meeting	Lead:	N/A

FIGURE 5-12. (Cont'd)

Day 2
(Day and Date)

FAA TEAM LEADER: **CONSORTIUM POC:**
PHONE NO. _____ **PHONE NO. _____**

Time	Activity	FAA Staff	Employer Staff
8:30 - 12:00 p.m.	• Recordkeeping and Reporting	Lead:	(As Appropriate)
12:00 - 1:00 p.m.	• Lunch		
1:30 - 2:30 p.m.	• MRO	Lead:	
2:30 - 5:00 p.m.	• Team Meeting	Lead:	N/A

Day 3
(Day and Date)

8:30 - 11:30 a.m.	• Followup Inspection Activity	Lead:	
11:30 - 12:30 p.m.	• Lunch		
1:00 - 3:00 p.m.	• Outbriefing	Lead:	

FIGURE 5-13. ENCLOSURE 3 - DOCUMENTS TO BE SENT TO THE FAA

_____ [1]	Contracts with collection site(s), laboratory(s), medical review officer (MRO), and employee assistance program (EAP) service provider; if applicable.
_____	A list of the names, addresses, points of contact and telephone numbers of all aviation employers who are consortium members.
_____	Internal policies and procedures for the anti-drug program.
_____	A sample of the drug testing custody and control form in use.
_____	Written instructions provided to specimen collectors.
_____	The number of blind performance test specimens submitted during the previous 12 months and a summary of the results, if you provide this service for consortium members.
_____	Completed Points of Contact form and Document/Record Custodians and Repository Locations form.
_____	Documents should be sent to the following address:

Team Leader's Address Here

[1] These documents do not need to be sent to the FAA, but they must be available at the inspection site for FAA review at the time of the inspection.

FIGURE 5-14. ENCLOSURE 4 -FAA DRUG ABATEMENT COMPLIANCE INSPECTION POINTS OF CONTACT

Consortium Name _____ **Date** _____

Inspection Topic	Point of Contact - Name/Title	Location/Address/ Phone No.
1. Employer Administrative and Quality Assurance Activities		
2. Specimen Collection Sites (use continuation sheet if needed) a. b. c.		
3. Medical Review Officer (use continuation sheet if needed)		
4. EAP		
5. Recordkeeping & Reporting		
6. Other (as appropriate)		

Remarks:

FIGURE 5-15. ENCLOSURE 5 - DOCUMENT/RECORD CUSTODIANS AND REPOSITORY LOCATIONS

In addition to the information/documents previously requested, please identify the custodian and his/her phone number and the repository locations for each of the items listed below, if retained by the consortium.

Document/Record	Custodian Name	Custodian Telephone	Repository Location Building/Room/ Address
1. Individual Training Records			
2. Training Lesson Plans, Rosters, and Posters/Handouts/Aids			
3. Specimen Collection Logs			
4. Chain of Custody Forms			
5. Individual Drug Test Results			
6. MRO Determination Documentation and Part 67 Notifications to the Air Surgeon			
7. Quality Assurance Blind Testing Results			
8. Random Selection Documentation			

FIGURE 5-15. (Cont'd)

Document/Record	Custodian Name	Custodian Telephone	Repository Location Building/Room/ Address
9. Documentation for Reasonable Cause and Post-Accident Tests			
10. Documents pertaining to drug testing arbitration or litigation			
11. Complaints concerning the anti-drug program			
12. Records of the Disposition of Positive Drug Test Cases			
13. MRO Correspondence			
14. Laboratory Correspondence			
15. Consortium Aviation Member Correspondence			

Section 4. Summary of Important Regulatory Factors

105. General. This summary serves as a quick reference for the inspector in the field during inspections. The summary lists, by element, key information from the Appendices of this handbook by topic area. This summary is not meant to be all inclusive, but is a handy reminder of key requirements from 14 CFR Part 61 et al and 49 CFR Part 40. The checklists in the Appendices and these two regulations should be referenced throughout the inspection process as specific items of compliance are evaluated.

106. EMPLOYER ADMINISTRATIVE AND QUALITY ASSURANCE ACTIVITIES

a. There are **FIVE (5)** prohibited drugs: marijuana, cocaine, opiates, phencyclidine, and amphetamines.

b. **Post-accident testing** is conducted as soon as possible but no later than **32 HOURS** after the accident.

c. **Return-to-duty testing** shall be performed on an unannounced basis for a period of not more than **60 MONTHS.**

d. **TWO (2) SUPERVISORS**, one of whom is trained in detection of the symptoms of drug use, must substantiate and concur in the decision to test an employee who is **reasonably suspected of drug use**, for **Part 121 employers and Part 135** employers with **more than 50 covered employees.**

e. **ONE (1) SUPERVISOR**, who is trained in detection of the symptoms of drug use, may decide to test an employee who is **reasonably suspected of drug use**, for **Part 135** employers **with 50 or fewer covered employees.**

f. The **employer** shall submit **THREE (3)** blind performance test specimens for each **100** employee specimens submitted up to a maximum of **100 blind performance test specimens per quarter.**

g. An **employer** with **2000** or more covered employees shall submit approximately **80 PERCENT** of their **blind performance test samples as blank.** The remaining performance specimens must be positive for one or more of the five specified drugs.

h. After the unannounced testing program based on **random selection** has been implemented for **12 months**, the number of random tests performed is not less than **50 percent** of the total number of covered employees on an annualized basis.

i. Do all employees who perform the functions listed below participate in the drug testing program?

(1) Flight crew-member duties
(2) Flight attendant duties
(3) Flight instruction or ground instruction duties
(4) Flight test duties
(5) Aircraft maintenance or preventive maintenance duties
(6) Aircraft dispatcher duties
(7) Aviation security or screening duties
(8) Non-military and non-FAA air traffic control duties.

107. SPECIMEN COLLECTION

a. The **specimen temperature** should be read within **FOUR (4) MINUTES** and the specimen shall be within the range of **32.5° - 37.7°C/90.5°- 99.8°F**.

b. An **observed collection** of a second specimen **shall be** conducted as soon as possible if:

(1) The employee has presented a specimen that falls outside the normal temperature range (32.5° - 37.7° C/90.5° - 99.8°) and either declines to provide measurement of oral body temperature or provides an oral body temperature that varies by more than 1° C/1.8°F from the temperature of the specimen, or

(2) The collection site person observes conduct clearly and unequivocally indicating an attempt to adulterate or substitute the sample.

c. An **observed collection** is **permitted** if:

(1) The **last urine specimen** provided by the donor was determined by the laboratory to have a specific gravity of less than **1.003** and a creatinine concentration below 0.2 g/l, or

(2) The donor has previously been determined to have used a controlled substance without medical authorization and the particular test was being conducted under a DOT agency regulation providing for return-to-duty testing.

d. All collected specimens must be at least **60 ml**.

e. In any case where a collection is monitored by **non-medical personnel** or is directly observed, the collection site person shall be the **same gender** as the donor.

f. For **post-accident or reasonable cause** collections if the specimen is not **at least 60 milliliters** the donor will be instructed to drink fluids for up to **EIGHT (8) HOURS**.

g. Copies **1** and **2** of the **Chain of Custody Forms** are sent with the specimen(s) to the testing laboratory; copies **3** through **6** are sent to the MRO, donor, collector and employer representative, respectively. Copy **7** is used only for split samples.

h. The employee may have altered or substituted the specimen if the **urine specimen** has a specific gravity of less than **1.003** and a **creatinine concentration** below **0.2 g/l**.

108. MEDICAL REVIEW OFFICER ACTIVITIES

a. The **laboratory** should report test results to the **employer's MRO** within an **average** of **FIVE (5)** working days after receipt of the specimen by the laboratory.

b. The **MRO** should **contact the employee** within a reasonable amount of time after he/she receives the testing results from the laboratory.

c. The **MRO** shall request a reanalysis of the original specimen producing the positive test result **if** the tested individual submits a **written request** to the MRO **no later than 60** days after receipt of notification of a confirmed positive test result.

d. The MRO shall authorize analysis of a split sample, if requested to do so by the employee within **72 hours** of the employee's having received actual notice of the confirmed positive test.

e. Initial test result cutoff levels.

Drug/Metabolite Cutoff Levels

	Initial test cutoff levels (ng/ml)	Confirmatory test cutoff levels (ng/ml)
Marijuana metabolites	**100**	**15**
Cocaine metabolites	**300**	**150**
Opiate metabolites	**300***	**300**
Phencyclidine	**25**	**25**
Amphetamines	**1000**	**500**

***25** ng/ml if immunoassay specific for free morphine.

109. EMPLOYEE ASSISTANCE PROGRAM

a. The following materials shall be displayed and distributed to all covered employees:

(1) Informational materials concerning drug abuse
(2) A community service hotline telephone number for employee assistance
(3)The employer's policy regarding drug use in the workplace.

b. Training for all employees in covered positions will include the following items:

(1) Effects and consequences of drug use on personal health, safety, and work environment
(2) Manifestations and behavioral cues that may indicate drug use and abuse
(3) Documentation of training, including names of persons receiving the training, the dates they received training, and what the training consisted of.

c. **Supervisors** who are in a position to require testing of employees for **reasonable cause** shall receive a **minimum** of **60 MINUTES of initial training** in addition to the general employee education.

d. **Supervisors** who are in a position to require testing of employees for **reasonable cause** shall participate in a **recurrent training program.**

110. RECORDKEEPING AND REPORTING

a. **Semiannual/annual reports** must be submitted within **45** days following the end of the specified period.

b. The **employer** will submit to the FAA:

(1) **Semiannual report** for the period **JANUARY 1 - JUNE 30** is due no later than August 15 of the _____year.

(2) **Annual report** for the period **JANUARY 1 - DECEMBER 31** is due no later than February 15, of the following year.

(3) Each report will summarize the results of the drug testing program for that period.

c. These reports will include the following information:

(1) Total number of tests performed and the total number of tests performed for each category of test

(2) Total number of positive test results by category of test, by function, by type of drug

(3) Disposition of an individual who failed or refused a drug test, by each category of test

(4) A summary of any negative finding based on scientific insufficiency which does not include any personal identifying information.

d. Does the **employer** maintain:

(1) Negative test results for **ONE (1) YEAR?**
(2) All records related to the collection process including Logbooks and certification statements for **TWO (2) YEARS?**
(3) Positive test results and rehabilitation records for **FIVE (5) YEARS?**

e. Does the **laboratory** provide **to the employer** a monthly statistical summary of urinalysis testing **within 14 calendar days** after the end of the month covered by the summary?

f. The **laboratory** will maintain and make available **documentation** of all aspects of the testing process for **at least TWO (2)** years.

111.-114. RESERVED.

Section 5. Random Selection

115. RANDOM SELECTION. This is the process of selecting personnel from the **covered employee pool** for drug testing so that each covered employee has an **equal** chance of being selected **each** time the process is conducted.

116. THE PROBABILITY OF SELECTION for an individual should be approximately equal to the **target annualized rate** for program divided by the number of times the random selection process is carried out each year.

117. ALL COVERED EMPLOYEES must be included in the covered employee pool **each** time the random selection process is carried out.

118. COMMON ERRORS IN RANDOM SELECTION. Differences in selection practices generally arise from a misunderstanding of the scientific basis of random selection, or from a desire to minimize operational difficulties and schedule disruptions for the employer and employees. Many of these differences result in errors. Some of the more common errors are:

a. **Flight crew testing:** Many carriers select crews of flights terminating at a central hub for testing. Because flight crew members often "bid" for certain flights based on seniority, this approach can result in senior personnel being subject to testing much less frequently than junior personnel. One way to avoid this problem is to select randomly from the pool on a regular schedule, but to conduct the actual specimen collection on the first available work day. Or the carrier can select from the entire pool and require persons to report to a hub location or establish satellite collection sites as needed.

b. **Select a replacement for testing when the selected person is on vacation:** Senior personnel accrue more vacation annually and therefore can more often be unavailable for testing when their names are selected. This can be avoided by testing at the first opportunity upon return to work rather than selecting a replacement person for testing.

c. **Testing only during one shift:** Some employers may schedule specimen collections only during normal working hours to accommodate collection site hours of operation. Employers who have fixed rather than rotating shifts must ensure that persons from all shifts are included in the selection process.

119.- RESERVED.

Section 6. Inspection Forms

120. INSPECTION FORMS. This section contains the following sample inspection forms and guides for use by inspection team members:

a. Figure 5-16, Employee Interview Guide.

b. Figure 5-17, FAA Anti-Drug Program Compliance Inspection Witness Statement Form

c. Figure 5-18, Documents Reviewed by FAA Team Members

d. Figure 5-19, Certificate of Authenticity

121.-126. RESERVED.

FIGURE 5-16. EMPLOYEE INTERVIEW GUIDE

Employer/Carrier _____ Date/Time_____

Interviewer Name _____

Interviewee Name (Optional) _____

Job Title _____

Length of Service_____

The following questions are intended to evaluate employee knowledge of the anti-drug training and general knowledge of the employer's program. The interviewer may paraphrase, modify, add to, or delete any of these questions as appropriate to circumstances. The privacy and confidentiality of the interview should be maintained by conducting the interview in a private setting with the interviewee's understanding that participation in the interview is strictly voluntary.

1. What is the general nature of your work assignment/duties?

2. What general training have you received concerning the anti-drug program? When was training conducted? What was the general format and nature of the training and its duration?

3. Are you aware of: (a) effects and consequences of drug use on personal health, safety and the work environment, and (b) manifestations and behavioral cues that may indicate drug use and abuse?

4. Are you aware of, or have you received, and can you describe examples of the following displayed or distributed items of information: (a) informational materials (posters, handouts, etc.) concerning drug abuse, (b) a community service hotline number for employee assistance, and (c) your employer's policy regarding drug use in the workplace?

FIGURE 5-16. (Cont'd)

5. **(For supervisors only)** Have you received additional training concerning reasonable cause testing referrals? When was this training conducted? Describe training. Indicate if the following was described:

   ___ Specific indicators of drug use

   ___ Contemporaneous physical indicators of drug use

   ___ Behavioral indicators of drug use

   ___ Performance indicators of drug use.

6. **(For supervisors only)** If not revealed in questions 5, were the following subjects addressed in the supervisor training: the specific, contemporaneous physical, behavioral, and performance indicators of probable drug use?

7. **(For supervisors only)** Have you received recurrent training covering the subject matter described in question 6? How often is this conducted? When was training last conducted?

8. Have you ever been the subject of a drug test? If so, what type of testing was conducted and when?

9. What is your general feeling concerning your employer's anti-drug program?

10. Do you have any questions, concerns, or complaints about your employer's anti-drug program?

FIGURE 5-17. FAA ANTI-DRUG PROGRAM COMPLAINCE INSPECTION WITNESS STATEMENT FORM

Name of
Company/Consortium:_____

Witness name:_____ Date:_____

Address:_____ Time:_____

Telephone: (Home) _____ (Work) _____ Place:_____

Inspector's name:_____

Others Present:_____

_____

Narrative:

_____

_____

_____

_____

_____

_____

_____

_____

Witness Signature:_____

Inspector's Signature:_____ page _____ of _____

FIGURE 5-17. WITNESS STATEMENT FORM (CONTINUATION SHEET)

Narrative:

Witness Signature:_____

Inspector's Signature:_____ page _____ of _____

FIGURE 5-18. DOCUMENTS REVIEWED BY FAA TEAM MEMBERS

Date/ Time	Document	Location	Reviewed by	Copies Made

FIGURE 5-19. CERTIFICATE OF AUTHENTICITY

I, _____

certify that this is a true and complete copy or duplicate of:

_____

_____

located at: _____

_____

Date: _____

Signature: _____

Office: _____

Section 7. Sample Warning Notice

127. General. This section provides a sample Warning Notice. The Warning Notice is a letter addressed to the alleged violator which (a) brings to the attention of the alleged violator facts and circumstances of the incident; (b) advises that, on the basis of available information, such operations or practices are contrary to the regulations; (c) states that the matter has been corrected and/or does not warrant legal enforcement action; and (d) requests future compliance with the regulations. Guidance concerning the proper use and formatting of Warning Notices can be found in Order 2150.3A.

FIGURE 5-20. SAMPLE WARNING NOTICE

File No. _____

Mr. JOHN DOE, PRESIDENT
EMPLOYER/CONSORTIUM
ADDRESS
CITY, STATE, ZIP CODE

Dear Mr. Doe:

On **(DATE)**, representatives of the Federal Aviation Administration (FAA) conducted an inspection of **(EMPLOYER NAME)**'s anti-drug program to determine **(EMPLOYER NAME)**'s compliance with 49 CFR Part 40 and 14 CFR Part 61 et al.

At the end of the inspection, **(EMPLOYER NAME)** was advised that the following practices were not in compliance with the regulations:

1. _____
_____
_____

2. _____
_____
_____

The practices listed above have either been corrected or do not warrant legal enforcement action at this time.

If you wish to add any information in explanation or mitigation, please submit it to me at **(REGIONAL ADDRESS)**. We will expect your future compliance with the regulations.

Sincerely,

(REGIONAL DRUG ABATEMENT PROGRAM MANAGER)

cc: (Employer/Consortium Anti-Drug Program Manager)

Section 8. Sample Employer/Consortium Letter of Correction

128. General. This section provides a sample Letter of Correction for use by the team leader in notifying the inspected employer/consortium of the results of the inspection. The Letter of Correction is intended for use when there is agreement with the company or organization that corrective action is acceptable to the FAA has been taken, or will be taken, within a reasonable time. The Letter of Correction usually confirms a discussion with the person involved in which a violation(s) is/are acknowledged and appropriate corrective action initiated. The sole purpose of a Letter of Correction is to correct conditions which are in violation of the Federal Aviation Regulations. The Letter of Correction generally should be forwarded to the inspected employer or consortium within 2 weeks following the inspection unless unresolved issues require additional review. Guidance concerning the proper use and formatting of Letters of Correction can be found in Order 2150.3A.

FIGURE 5-21. SAMPLE LETTER OF CORRECTION

File No. _____

MR. JOHN DOE, PRESIDENT
EMPLOYER/CONSORTIUM
ADDRESS
CITY, STATE ZIP CODE

Dear Mr. Doe:

On **(DATE)**, representatives of the Federal Aviation Administration (FAA) conducted an inspection of **(EMPLOYER NAME)**'s anti-drug program to determine **(EMPLOYER NAME)**'s compliance with 49 CFR Part 40 and 14 CFR Part 61, et al. As detailed below, the inspection revealed that **(EMPLOYER NAME)**'s anti-drug program did not comply with these regulations.

TEXT _____

_____

_____

_____

CORRECTIVE ACTION: _____

_____

_____

_____

You must submit to the FAA, documentation which demonstrates that you have corrected the out-of-compliance issues addressed in this letter within the time frames listed. This documentation must be received by the FAA not later than **(DATE)**.

Send the required documentation to: **(TEAM LEADER'S ADDRESS)**. If you have any questions regarding this inspection, please contact **(TEAM LEADER)** at **(PHONE NUMBER)**.

FIGURE 5-21. SAMPLE LETTER OF CORRECTION (Cont'd)

We have given consideration to all available facts and concluded that this matter does not warrant legal enforcement action. In lieu of such action, we are issuing this letter which will be made a matter of record. We expect that in the future **(EMPLOYER NAME)**'s anti-drug program will be in compliance with all applicable regulations.

Sincerely,

(REGIONAL DRUG ABATEMENT PROGRAM MANAGER)

cc: (Employer/Consortium Anti-Drug Program Manager)

Section 9. Sample Letter of Investigation

129. General. The Letter of Investigation is a letter used to notify, in writing, an alleged violator of an agency investigation. The letter should state that an agency investigation is being conducted, inform the alleged violator of the activities being investigated, and should invite comments from the alleged violator on the circumstances of the incident(s). Guidance concerning the proper use and formatting of Letters of Investigation can be found in Order 2150.3A.

FIGURE 5-22. SAMPLE LETTER OF INVESTIGATION

File No. _____

MR. JOHN DOE, PRESIDENT
EMPLOYER/CONSORTIUM
ADDRESS
CITY, STATE, ZIP CODE

Dear Mr. Doe:

On **(DATE)**, representatives of the Federal Aviation Administration (FAA) conducted an inspection of **(EMPLOYER NAME)**'s anti-drug program to determine **(EMPLOYER NAME)**'s compliance with 49 CFR Part 40 and 14 CFR Part 61 et al. During this inspection it was revealed that **(INSERT DESCRIPTION OF NONCOMPLIANCE).**

This is to inform you that this incident(s) is under investigation by the FAA. We wish to offer you the opportunity to discuss this violation(s) personally and/or submit a written statement. If you desire to do either, this should be accomplished within 10 days following receipt of this letter. Your statement should contain all pertinent facts and any mitigating circumstances which you believe may have a bearing on all incident(s).

Your written statement should be submitted to: **(TEAM LEADER'S ADDRESS)**. If you have any questions, please contact **(TEAM LEADER'S NAME)** at **(TEAM LEADER'S PHONE NUMBER).**

If we do not hear from you within the specified time, our report will be processed without the benefit of your statement.

Sincerely,

(REGIONAL DRUG ABATEMENT PROGRAM MANAGER)

cc: (Employer/Consortium Anti-Drug Program Manager)

Appendix 1. INTRODUCTION

APPENDICES OF INSPECTION PROCEDURES AND REFERENCES

These appendices contain individual inspection procedures and checklists for use by FAA inspectors in evaluating aviation employer compliance with anti-drug regulation requirements in each of the topical areas. Those topical areas and their checklists are contained in the following appendices:

Appendix 2 - Employer Administrative and Quality Assurance Activities

Appendix 3 - Specimen Collection

Appendix 4 - Medical Review Officer (MRO) Activities

Appendix 5 - Employee Assistance Program (EAP)

Appendix 6 - Recordkeeping and Reporting

These inspection procedures and checklists are to be used in conjunction with the inspection guidance provided in the Inspector's Guide, to assure that all applicable regulatory requirements are inspected and evaluated for compliance.

Appendix 2. INSPECTION PROCEDURES FOR EMPLOYER ADMINISTRATIVE AND QUALITY ASSURANCE ACTIVITIES

1. OBJECTIVE. The overall objective is to evaluate the methods and procedures used by the employer to define sensitive safety- and security-related positions and to select persons for testing under the prescribed categories (e.g., periodic, random, post-accident, reasonable cause, preemployment, return-to-duty).

In addition, the employer's current anti-drug plan will be examined to ensure that it is the same plan that is on file with the FAA.

Applicable DOT regulations and corresponding Inspection Elements are listed below.

Applicability	Regulatory Reference	Related Inspection Elements
• Anti-Drug Plan Review	14 CFR Part 121, Appendix I, II, IX	1.1
• Types of Testing	14 CFR Part 121, Appendix I, V	1.2
• Covered Functions	14 CFR Part 121, Appendix I, III	1.3
• Employer Quality Assurance Blind Testing of Laboratories	49 CFR Part 40.31(d)(1)	1.4
• Employer/Laboratory Contract	14 CFR Part 121, Appendix I 49 CFR Part 40.29(k)	1.5
• Employer/MRO Responsibilities	49 CFR Part 40.33(c)(3) and (4)	1.6

2. OVERVIEW. The employer's anti-drug plan should be the same as the plan on file with the FAA and should be current and complete. The provisions of the plan being implemented by the employer must have been reviewed and approved by the FAA, and no unauthorized changes should have been made. The various types of testing are intended to cover all potential incidents of prohibited drug use. Preemployment testing ensures that an employee is not using drugs when assigned to a covered position. Periodic testing ensures that all employees in safety- and security-related positions who hold medical certificates issued under Part 67 are tested at least once during the first year of random testing implementation. Random testing is designed to present every employee with an equal chance of being tested at any time, thus acting as a deterrent. Postaccident testing is to ascertain whether an employee involved in an accident may have used prohibited drugs. Reasonable cause testing is to confirm suspected drug use. Return-to-duty testing demonstrates the continuing absence of the five prohibited drugs in an employee who has previously tested positive on a drug test, or who has refused to submit to a drug test. Combined, these types of testing form a comprehensive program to detect and deter the use of prohibited drugs in the workplace.

The effectiveness of this program depends upon proper criteria for selection of the test subjects. All employees in sensitive safety- or security-related positions must be subject to the testing, and all must be tested fairly. Equity is maintained by ensuring that the testing procedures comply with regulations.

3. GENERAL APPROACH. The primary source of information regarding the employer's administrative and quality assurance activities will be the employer's own records. The following types of records shall be reviewed:

a. The employer's anti-drug plan to ensure that no unauthorized changes have been made to the approved plan on file with the FAA.

b. Employee records to ensure preemployment testing of every covered employee who is hired for or transferred into a covered position after the effective date of the employer's anti-drug program.

c. Employee records to ensure that periodic, reasonable cause, and return-to-duty testing are conducted as appropriate.

d. Documents supporting the random selection process to ensure that all appropriate employees are included at all times in the selection pool, that the correct number of employees is tested in a timely fashion, that testing is unannounced, and that testing is evenly distributed throughout the year.

e. Accident reports to ensure appropriate post-accident testing.

f. Documentation of the quality assurance blind testing program to ensure that the proper number of samples is submitted and that results are reviewed for accuracy.

4. INSPECTION ACTIVITIES. When conducting the on-site records inspection, the inspector should first introduce him/herself and explain to the person responsible for records retention the nature of the inspection activity and the reason for the inspection. For a no-notice inspection, on-duty personnel should be permitted to contact their supervisors and the employer representative to verify the authority of the inspection personnel prior to proceeding with the inspection.

Throughout the inspection process, the Inspection Elements should be referenced to ensure that inspected items and procedures comply with regulatory requirements. The Checklist of Inspection Elements for this topic is found in Attachment 1. Both noteworthy and deficient observations should be identified in writing. Clarification of observations with employer personnel may be warranted to verify an apparent item of non-compliance, but identifying an observation as an item of non-compliance to the employer should be avoided until completion of all inspection activity, since additional information may be revealed later that modifies or contradicts an apparent observation.

Whenever possible, observations should be based on physical inspection and observable evidence. For example, incidents of post-accident testing should be verified for both the appropriate definition of an accident and the actions of the employer. Reasonable cause testing should be justifiably based on specific contemporaneous physical, behavioral, or performance indicators of drug use. All covered employees must be included in the pool for random testing selection at all times. Verbal descriptions or assertions by employer staff members on these or other inspection elements should not be relied on or favored over documentation.

5. REVIEW OF RESULTS. Informal meetings should be held each day at the conclusion of inspection activity to review the information gathered and, if necessary, to resolve any differences between the inspection team members' understanding of the facts.

At the conclusion of the on-site inspection, all observations should be reviewed verbally with the employer to allow for clarifications and provide the employer with an understanding of the inspection results. Any possible sanctions which may result from items of non-compliance should <u>not</u> be discussed, since this determination must be reviewed and approved by headquarters.

6. REPORT WRITING. The individual inspector(s) assigned responsibility for inspecting the topic of Employer Administrative and Quality Assurance Activities is responsible for completing the Checklist of Inspection Elements for Employer Administrative and Quality Assurance Activities found in Figure 1. Items of non-compliance should be noted as statements of fact based on observations made at the time of the inspection and generally will correlate directly to individual Inspection Elements from the Checklist. Thus, the report input represents the current status of the program and not what the inspected entity intends to do or correct in the future. Where appropriate, future plans for corrective action may be noted; however, all items of non-compliance will be noted as statements of fact.

In addition to deficiencies, noteworthy practices should be identified for future dissemination to the industry. In support of individual observations, a brief analysis may be warranted to describe its relationship to, and impact on, overall program performance. When analysis is deemed necessary, it should follow the observation to which it relates. Report input will be provided to the inspection team leader at the daily meeting after the inspection process terminates.

FIGURE 1. CHECKLIST OF INSPECTION ELEMENTS FOR EMPLOYER ADMINISTRATIVE AND QUALITY ASSURANCE ACTIVITIES (14 CFR PART 121, APPENDIX I)

1.1 ANTI-DRUG PROGRAM PLAN REVIEW

☐ ☐ ☐ Yes No N/A

1.1.1 Does the employer ensure, with adequate documentation, that each employee who performs safety sensitive duties by contract for the employer is covered under an FAA-Approved plan? (14 CFR Part 121, Appendix I, II.)

1.2 TYPES OF TESTING

1.2.1 Does the employer conduct **preemployment** testing which includes the following elements?

☐ ☐ ☐ Yes No N/A

(a) All individuals pass a drug test in accordance with 14 CFR Part 121, Appendix I, for this employer prior to employment or assignment in a covered position. (14 CFR Part 121, Appendix I, V., A.)

☐ ☐ ☐ Yes No N/A

(b) Applicants are notified at the time of application that testing for marijuana, cocaine, opiates, phencyclidine (PCP) and amphetamines or a metabolite of those drugs is required for employment in covered positions. (14 CFR Part 121, Appendix I, V., A.)

FIGURE 1. (Cont'd)

1.2.2 Does the employer conduct **periodic** testing which includes the following elements?

☐ ☐ ☐
Yes No N/A

(a) Each employee who performs a covered function and who is required to undergo a medical examination under Part 67 submits to a drug test in conjunction with the first medical evaluation during the first calendar year of the implementation of the employer's anti-drug program, or in accordance with a procedure for collecting periodic specimens during the same time period as specified in the employer's plan. (14 CFR Part 121, Appendix I, V., B.)

☐ ☐ ☐
Yes No N/A

(b) Periodic testing is continued through the first 12 months of the implementation of the drug testing program until unannounced testing based on random employee selection is fully implemented. (14 CFR Part 121, Appendix I, V., B.)

1.2.3 Does the employer conduct **random** testing which includes the following elements?

☐ ☐ ☐
Yes No N/A

(a) The total number of unannounced tests based on random selection of employees during the first 12 months of the implementation of the unannounced testing program is not less than 25 percent of the number of employees performing covered functions. (14 CFR Part 121, Appendix I, V., C.,(1)(c))

☐ ☐ ☐
Yes No N/A

(b) Unannounced tests based on random selection are reasonably spaced throughout the year. (14 CFR Part 121, Appendix I, V., C.,(1)(a))

FIGURE 1. (Cont'd)

☐ ☐ ☐
Yes No N/A

(c) The number of employees in covered positions randomly selected for unannounced testing in the final test at the end of the first 12 months of the implementation of the unannounced testing program is equal to an annualized rate of not less than 50 percent of the total number of covered employees. (14 CFR Part 121, Appendix I, V., C.,(1)(b))

☐ ☐ ☐
Yes No N/A

(d) After the unannounced testing program based on random selection has been implemented for 12 months, the number of tests conducted is not less than 50 percent of the total number of covered employees on an annualized basis. (14 CFR Part 121, Appendix I, V., C.,(2))

☐ ☐ ☐
Yes No N/A

(e) The random selection procedure is based on a random table or on a computer-based number generation system, or another method meeting the approval of the FAA as indicated by plan approval. (14 CFR Part 121, Appendix I, V., C.)

☐ ☐ ☐
Yes No N/A

(f) The annualized rate of unannounced testing on random selection is based on the total number of personnel in covered positions or by an alternative method specified in the approved drug testing plan. (14 CFR Part 121, Appendix I, II.)

1.2.4 Does the employer conduct **post-accident** testing in case of an accident (as defined in 14 CFR Part 121, Appendix I, II) which includes the following elements? *["Accident" means an occurrence associated with the operation of an aircraft which takes place between the time any person boards the aircraft with the intention of flight and all such persons have disembarked, and in which any person suffers death or serious injury, or in which the aircraft receives substantial damage (49 CFR Part 830.2)]*

FIGURE 1. (Cont'd)

☐ ☐ ☐
Yes No N/A

(a) Testing is conducted when an employee's performance either contributed to an accident or cannot be completely discounted as contributing to an accident. (14 CFR Part 121, Appendix I, V., D.)

☐ ☐ ☐
Yes No N/A

(b) Testing is conducted as soon as possible, but no later than 32 hours after the accident. (14 CFR Part 121, Appendix I, V., D.)

☐ ☐ ☐
Yes No N/A

(c) The employer's decisions not to test have been based upon the determination, using the best information available at the time of the accident, that the employee's performance could not have contributed to the accident. (14 CFR Part 121, Appendix I, V., D.)

1.2.5 Under appropriate circumstances, does the employer conduct **reasonable cause** testing which includes the following elements?

☐ ☐ ☐
Yes No N/A

(a) Each employee who performs a covered function, and who is reasonably suspected of using a prohibited drug, is tested for the presence of drugs in accordance with the regulations. (14 CFR Part 121, Appendix I, V., E.)

☐ ☐ ☐
Yes No N/A

(b) The employer does not test for drugs other than those listed in 49 CFR Part 40 unless it has received prior approval from the FAA, and DHHS has established an approved testing protocol and positive threshold for each such additional drug. (49 CFR Part 40.21(b)) (14 CFR Part 121, Appendix I, IV.) (14 CFR Part 121, Appendix I, V., E.)

FIGURE 1. (Cont'd)

☐ ☐ ☐
Yes No N/A

(c) At least two supervisors, one of whom is trained in detection of the symptoms of drug use, substantiate and concur in the decision to test an employee who is reasonably suspected of drug use, for Part 121 employers and Part 135 employers with more than 50 covered employees. (14 CFR Part 121, Appendix I, V., E.)

☐ ☐ ☐
Yes No N/A

(d) At least one supervisor, trained in detection of the symptoms of drug use, decides to test employees who are reasonably suspected of drug use for Part 135 employers with 50 or fewer covered employees. (14 CFR Part 121, Appendix I, V., E.)

☐ ☐ ☐
Yes No N/A

(e) Decisions to test are reasonable and articulable, and based on specific contemporaneous physical, behavioral or performance indicators of probable drug use. (14 CFR Part 121, Appendix I, V., E.)

1.2.6 Under appropriate circumstances, does the employer conduct **return-to-duty** testing which includes the following elements?

☐ ☐ ☐
Yes No N/A

(a) All employees in covered positions who have been hired or have returned to duty after having failed a FAA-mandated drug test, or who have refused to submit to a FAA-mandated drug test, are subject to a program of unannounced return-to-duty testing. (14 CFR Part 121, Appendix I, V., F.)

☐ ☐ ☐
Yes No N/A

(b) Return-to-duty testing is performed on an unannounced basis, at a frequency established by the MRO, for a period of not more than 60 months. (14 CFR Part 121, Appendix I, V., F.)

FIGURE 1. (Cont'd)

1.3 COVERED FUNCTIONS

1.3.1 Do all employees who perform the functions listed below participate in the drug testing program?

☐ ☐ ☐ Yes No N/A (a) Flight crew-member duties

☐ ☐ ☐ Yes No N/A (b) Flight attendant duties

☐ ☐ ☐ Yes No N/A (c) Flight instruction or ground instruction duties

☐ ☐ ☐ Yes No N/A (d) Flight test duties

☐ ☐ ☐ Yes No N/A (e) Aircraft maintenance or preventative maintenance duties

☐ ☐ ☐ Yes No N/A (f) Aircraft dispatcher duties

☐ ☐ ☐ Yes No N/A (g) Aviation security or screening duties

FIGURE 1. (Cont'd)

Yes No N/A

(h) Non-military and non-FAA air traffic control duties.

(14 CFR Part 121, Appendix I, III.)

1.4 EMPLOYER QUALITY ASSURANCE BLIND TESTING OF LABORATORIES

Yes No N/A

1.4.1 Does the employer submit three blind performance test specimens for each 100 employee specimens submitted up to a maximum of 100 blind performance test specimens submitted per quarter? (The FAA may increase the maximum number of samples if doing so is necessary to ensure adequate quality control of employers or consortia with very large numbers of employees.) (49 CFR Part 40.31 (d)(2))

Yes No N/A

1.4.2 For an employer with 2000 or more covered employees, are approximately 80 percent of the blind performance test samples blank (i.e., containing no drug or otherwise as approved by the FAA) and are the remaining samples positive for one or more drugs per sample in a distribution such that all the drugs to be tested are included in approximately equal frequencies of challenge? Are the positive samples spiked only with those drugs for which the employer is testing (but may include spiking with other [potentially interfering] compounds, as technically appropriate, in order to verify the specificity of a particular essay)? (49 CFR Part 40.31 (d)(3))

Yes No N/A

1.4.3 Do employers with fewer than 2000 covered employees submit blind performance test specimens as provided in 1.4.2 above or submit only blank samples or submit two separately labeled portions of a specimen from the same non-covered employee? (49 CFR Part 40.31 (d)(4))

FIGURE 1. (Cont'd)

☐ ☐ ☐ Yes No N/A

1.4.4 If a consortium is used, does the consortium submit blind samples on behalf of its members and is the blind sampling rate applied to the total number of specimens submitted by the consortium? (49 CFR Part 40.31 (d)(5))

☐ ☐ ☐ Yes No N/A

1.4.5 In the event of a determination of an unsatisfactory performance testing result based on an investigation by the FAA or DHHS, does the laboratory take immediate action which corrects the cause of the unsatisfactory performance testing result? Does the individual responsible for the day-to-day management and operation of the drug testing laboratory sign and date the FAA or DHHS record of the investigation findings and the corrective action(s) taken? (49 CFR Part 40.31 (d)(6))

☐ ☐ ☐ Yes No N/A

1.4.6 If a false positive error occurs on a blind performance test specimen and the error is determined to be an administrative error (clerical, sample mixup, etc.), does the employer promptly notify the FAA, and does the employer require the laboratory to take corrective action to minimize the occurrence of the particular error in the future? (If there is reason to believe the error could have been systemic, the FAA may also require review and reanalysis of previously run specimens.) (49 CFR Part 40.31 (d)(7))

☐ ☐ ☐ Yes No N/A

1.4.7 If a false positive error occurs on a blind performance test specimen and the error is determined to be a technical or methodological error, does the employer instruct the laboratory to submit all quality control data from the batch of specimens which included the false positive specimen to the FAA? In addition, does the laboratory retest all specimens analyzed positive for that drug or metabolite from the time of final resolution of the error back to the time of the last satisfactory performance test cycle? *(This retesting is documented by a statement signed by the individual responsible for day-to-day management of the laboratory's urine drug testing. The FAA may require an on-site review of the laboratory which may be conducted unannounced during any hours of operation of the laboratory. Based on information provided by the FAA, DHHS has the option of revoking or suspending the laboratory's certification or recommending that no further action be taken if the case is one of less serious error in which corrective action has already been taken, thus reasonably assuring that the error will not occur again.)* (49 CFR Part 40.31 (d)(8))

FIGURE 1. (Cont'd)

1.5 EMPLOYER/LABORATORY CONTRACT

☐ ☐ ☐ Yes No N/A

1.5.1 Is the employer's contracted laboratory certified by DHHS? (14 CFR Part 121, Appendix I, I.)

☐ ☐ ☐ Yes No N/A

1.5.2 Does the laboratory comply with all applicable provisions of any State licensing requirements? (49 CFR Part 40.29 (k)(1))

☐ ☐ ☐ Yes No N/A

1.5.3 Does the laboratory, in compliance with its DHHS certification, have the capability at the same laboratory premises of performing the initial and confirmatory tests for each drug or metabolite for which service is offered? (49 CFR Part 40.29 (k)(2))

☐ ☐ ☐ Yes No N/A

1.5.4 Does the laboratory allow inspection, planned or unannounced, of its facility by the Secretary, the FAA, any employer utilizing the laboratory and DHHS or any organization performing laboratory certification on behalf of DHHS at any time including pre-award inspections? (49 CFR Part 40.29 (l)) and (14 CFR Part 121, Appendix I, VI.,(b))

☐ ☐ ☐ Yes No N/A

1.5.5 Does the contract require that the laboratory maintain employee test records in confidence, as provided in FAA and DOT regulations? Does the contract provide that the laboratory shall disclose information related to a positive drug test of an individual to the individual, the employer, or the decisionmaker in a lawsuit, grievance, or other proceeding initiated by or on behalf of the individual and arising from a certified positive drug test? (49 CFR Part 40.35)

FIGURE 1. (Cont'd)

1.6 EMPLOYER/MRO RESPONSIBILITIES

Yes	No	N/A		
☐	☐	☐	1.6.1	Does the management official ensure, to the maximum extent practicable, that the employee's contact with the MRO is held in confidence? If the management official is unable to contact the employee, after making all reasonable efforts, is the employee placed on temporary unqualified status or medical leave by the employer? (49 CFR Part 40.33 (c)(3) and (4))

Appendix 3. INSPECTION PROCEDURES FOR SPECIMEN COLLECTION

1. OBJECTIVE. The objective is to evaluate the performance of collection site personnel and to assess the adequacy of facility security, training, supplies and documentation to assure the integrity and confidentiality of the urine specimen collection process.

Applicable DOT regulations and corresponding Inspection Elements are listed below.

Applicability	Regulatory Reference	Related Inspection Elements
• Procedures, Instructions & Training	49 CFR Part 40.23	2.1
• Chain of Custody Forms	49 CFR Part 40.23 (a)	2.2
• Specimen Bottles, Sealing Systems and Shipping Containers	49 CFR Part 40.23 (b)	2.3
• Specimen Collection Sites, Equipment and Security	49 CFR Part 40.25 (a),(b),(d)	2.4
• Specimen Collection Procedures	49 CFR Part 40.25 (e),(f)	2.5

2. OVERVIEW. The specimen collection process is one of the more critical and sensitive areas of the overall anti-drug program. It is in this process that errors in specimen custody and control are most likely to occur and concerns over individual privacy, confidentiality, and personal dignity to arise if collection procedures are not carried out in an efficient and professional manner. It is during urine specimen collection that individual participation in the drug testing process is required of the donor.

Collection sites must have trained and knowledgeable staff and all required materials, equipment, and facilities to provide for collection, security, temporary storage, and shipping of urine specimens to certified drug testing laboratories.

3. GENERAL APPROACH. Since specimen collection involves a series of physical processes and actions, the only effective method for evaluation is to conduct an on-site inspection of the activity. This inspection should include the following activities:

a. A thorough review of the written protocol governing the collection process

b. Inquiry into the training and qualifications of collection site staff

c. Physical inspection of the collection site facilities to ensure that the configuration, equipment, and security of the site are adequate

d. Inspection of the custody and control forms, collection supplies (e.g., collection containers and specimen bottles), and shipping containers to ensure that they meet regulatory requirements

e. Observation of the actual collection process (excluding observation of urination) for an employee being tested (if there are no objections by the donor or collection staff), or participation of the inspector in a mock collection which demonstrates all aspects of the process through preparation of the mock specimen for shipment to the testing laboratory. **In no case will inspectors provide an actual urine specimen.**

4. INSPECTION ACTIVITIES. In preparing for the evaluation, it is useful for the inspector to ask the employer whether any problems have been encountered at the collection site being inspected. Employee complaints, refusals to cooperate by employees, lost or unaccounted for specimens, instances of broken chains of custody, delays in shipping specimens, or rejections of specimens by the testing laboratory should be considered in preparing to inspect the site. Any apparent irregularities or improper past practices should receive special attention.

During the actual on-site inspection, the inspector should first introduce him/herself and explain to the collection site staff the nature of the inspection activity and the reason for the inspection. In the case of a no-notice inspection, on-duty collection site staff should be permitted to contact their supervisors and the employer representative to verify the authority of the inspection personnel prior to proceeding with the inspection activity.

It is generally useful to begin the inspection activity by reviewing the areas indicated in Items 1 through 5 of Section 3.0, prior to beginning the performance review of the actual collection process itself. This will familiarize the inspector with the knowledge of collection personnel and put them more at ease. Examination of the facility, equipment, supplies, documentation, and procedures will provide insight into areas which may warrant special attention when observing the actual collection process.

Throughout the inspection process, the inspector should refer to the Checklist of Inspection Elements to assure that inspected items and procedures comply with regulatory requirements. The Checklist of Inspection Elements for this topic is found in Figure 1. The Checklist is organized in a way that promotes logical examination, beginning with document reviews and facility inspections and concluding with observation of the actual collection process. Both noteworthy and deficient observations should be identified in writing, on the Checklist, as they are observed. Clarification of an observation with collection site personnel may be solicited as needed to verify an apparent item of non-compliance, but identifying an observation as an item of non-compliance to the employer should await completion of all inspection activity, since additional information may be revealed later in the inspection which partially or fully mitigates an apparent observation.

Whenever possible, observations should be based on empirical data, physical inspection, and observable evidence. Verbal descriptions or assertions by collection site staff should not be relied on to verify actual processes unless no other means of verification exists. In all cases, actual observation of the collection process should be conducted.

In some instances, collection site staff may indicate that they have experienced difficulties beyond their control. This might include late arrival of employees, inability to identify employees because of a lack of photo identification, problems with shipping or courier services, or unreasonable demands from the testing laboratory or MRO. In such cases, it may be necessary to verify these contentions with these entities. If the difficulty lies in an area being inspected by another inspector, coordination may be needed to resolve the issue and/or to assure that any observation is reported under the topic area where the responsibility lies.

5. REVIEW OF RESULTS. Informal review meetings should be held each day at the conclusion of inspection activity to review the information gathered and, if necessary, to resolve any differences between the inspectors' understanding of the facts.

At the conclusion of the on-site inspection, all observations should be reviewed verbally with the employer's representative to allow for clarifications and provide the employer with an understanding of the inspection results. Any possible sanctions which may result from items of non-compliance should <u>not</u> be discussed, since this determination must be reviewed and approved by headquarters.

6. REPORT WRITING. The individual inspector(s) assigned responsibility for inspecting the topic of Specimen Collection is responsible for completing the Checklist of Inspection Elements for Specimen Collection found in Figure 1. Items of non-compliance should be noted as statements of fact based on observations made at the time of the inspection and generally will correlate directly to individual Inspection Elements from the Checklist. Thus, the report input represents the current status of the program and not what the inspected entity intends to do or correct in the future. Where appropriate, future plans for corrective action may be noted; however, all items of non-compliance will be noted as statements of fact. In addition to deficiencies, noteworthy practices should be identified for future dissemination to the industry. In support of individual observations, a brief analysis may be warranted to describe its relationship to, and impact on, overall program performance. When an analysis is deemed necessary, it should follow the observation to which it relates. Report input will be provided to the inspection team leader at the daily meeting after the inspection process terminates.

FIGURE 1. CHECKLIST OF INSPECTION ELEMENTS FOR SPECIMEN COLLECTION

2.1 PROCEDURES, INSTRUCTIONS AND TRAINING

2.1.1 Do collection procedures and training clearly emphasize that the collection site person has the following responsibilities?

☐ ☐ ☐ Yes No N/A

(a) Maintaining the integrity of the specimen collection and transfer process

☐ ☐ ☐ Yes No N/A

(b) Carefully ensuring the modesty and privacy of the donor

☐ ☐ ☐ Yes No N/A

(c) Avoiding any conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.

(49 CFR Part 40.23 (d)(1))

☐ ☐ ☐ Yes No N/A

2.1.2 Do non-medical persons receive training and demonstrate proficiency prior to assuming collection site responsibilities? (Licensed medical professionals, technologists or technicians do not require special training if written instructions are provided and they perform collections in accordance with those instructions.) (49 CFR Part 40.23 (d)(2)(i))

☐ ☐ ☐ Yes No N/A

2.1.3 Are collection site persons provided detailed, clear instructions for specimen collection and are instructions on collection also provided to employer representatives and donors setting forth their responsibilities? (49 CFR Part 40.23 (d)(2)(ii))

FIGURE 1. (Cont'd)

☐ ☐ ☐ Yes No N/A

2.1.4 Does a direct supervisor of an employee not serve as the specimen collection person for that employee, unless it is impracticable for any other individual to perform the function? (49 CFR Part 40.23 (d)(3))

☐ ☐ ☐ Yes No N/A

2.1.5 Do procedures exist to ensure that post-accident specimen collection can be performed in all cases no later than 32 hours following the accident? (14 CFR Part 121, Appendix I, V., D.)

☐ ☐ ☐ Yes No N/A

2.1.6 In *any case* where a collection is monitored by non-medical personnel or is directly observed, is the collection site person of the same gender as the donor? A collection is monitored for this purpose if the enclosure provides less than complete privacy for the donor (e.g., if a restroom stall is used and the collection site person remains in the restroom, or if the collection site person is expected to listen for use of unsecured sources of water). (49 CFR Part 40.23 (d)(4))

2.2 CHAIN OF CUSTODY FORMS

☐ ☐ ☐ Yes No N/A

2.2.1 Does the employer utilize a multi-part, carbonless, standard drug testing custody and control form? (49 CFR Part 40.23 (a))

☐ ☐ ☐ Yes No N/A

2.2.2 Are copies 1 and 2 sent with the specimen(s) to the testing laboratory; are copies 3 through 6 sent to the MRO, donor, collector and employer representative, respectively? (49 CFR Part 40.23 (a))

FIGURE 1 (Cont'd)

☐ ☐ ☐ Yes No N/A

2.2.3 If used, does copy 7 accompany a "split specimen" to the original sample's laboratory or an alternative laboratory or an employer storage site, and is the identification number for the split specimen on Copy 7 a derivative of the original specimen identification number? (49 CFR Part 40.23 (a))

2.2.4 Does the following information appear on all parts of the form?

☐ ☐ ☐ Yes No N/A

(a) A pre-printed unique specimen identification number

☐ ☐ ☐ Yes No N/A

(b) The donor's employee identification or social security number

☐ ☐ ☐ Yes No N/A

(c) The employer's name, address and identification number

☐ ☐ ☐ Yes No N/A

(d) The MRO's name and address

☐ ☐ ☐ Yes No N/A

(e) The drugs for which testing is to be performed

☐ ☐ ☐ Yes No N/A

(f) The reason for testing (preemployment, random, etc.)

FIGURE 1. (Cont'd)

☐ ☐ ☐
Yes No N/A

(g) A block for the collector to indicate whether or not the temperature of the specimen was read within 4 minutes and whether the temperature was within the required range (32.5° - 37.7°C/90.5° - 99.8°F) and, if not, then the actual temperature of the specimen

☐ ☐ ☐
Yes No N/A

(h) Chain of custody block, including space for each transfer, purpose of transfer, released by (signature/print name), received by (signature/print name), date and the pre-printed words "Provide specimen for testing" and "DONOR"

☐ ☐ ☐
Yes No N/A

(i) Space for collector's name, date of collection, collection site location, remarks concerning unusual collection circumstances and whether a split sample was taken

☐ ☐ ☐
Yes No N/A

(j) A signature block for the collector with date and the following certification statement:

I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 3 of this form, that it bears the same identification number as that set forth above, and that it has been collected, labelled and sealed in accordance with applicable Federal requirements. (49 CFR Part 40.23 (a)(1))

FIGURE 1. (Cont'd)

2.2.5 Does the following information appear on specific copies of the form, as appropriate?

☐ ☐ ☐
Yes No N/A

(a) Space for laboratory analysis information on parts 1, 2, and 7, including accession number, laboratory name and address, remarks, test results, printed name and signature of the laboratory official, date and the following certification statement:

I certify that the specimen identified by this accession number is the same specimen that bears the identification number set forth above, that the specimen has been examined upon receipt, handled and analyzed in accordance with applicable Federal requirements, and that the results set forth below are for that specimen.

☐ ☐ ☐
Yes No N/A

(b) Space for MRO information on parts 1, 2, and 7, including name, address, signature, date and the following certification statement:

I have reviewed the laboratory results for the specimen identified by this form in accordance with applicable Federal requirements. My final determination/verification is:

☐ ☐ ☐
Yes No N/A

(c) Space for donor information on parts 3 through 5, including printed name, daytime phone number, date of birth, signature, date and the following statement:

I certify that I provided my urine specimen to the collector; that the specimen bottle was sealed with a tamper-proof seal in my presence; and that the information provided on this form and on the label affixed to the specimen bottle is correct.

FIGURE 1. (Cont'd)

☐ ☐ ☐
Yes No N/A

(d) A statement to the donor, as follows, on parts 3 and 4 of the form:

Should the results of the laboratory tests for the specimen identified by this form be confirmed positive, the Medical Review Officer will contact you to ask about prescriptions and over-the-counter medications you may have taken. Therefore, you may want to make a list of those medications as a "memory jogger." THIS LIST IS NOT NECESSARY. If you choose to make a list, do so either on a separate piece of paper or on the back of your copy (copy 4 - Donor) of this form -- DO NOT LIST ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE YOUR COPY WITH YOU.

☐ ☐ ☐
Yes No N/A

(e) The form may include additional information (for billing, etc.) but does *not* include personal identifying information other than the employee identification or social security number. (49 CFR Part 40.23 (a)(1) through (6))

2.3 SPECIMEN BOTTLES, SEALING SYSTEMS AND SHIPPING CONTAINERS

☐ ☐ ☐
Yes No N/A

2.3.1 Are collection containers (if used) and specimen bottles single-use with a sealed wrapper which is removed by the donor or collector in the presence of the donor? (49 CFR Part 40.23 (b)(1))

☐ ☐ ☐
Yes No N/A

2.3.2 Do the specimen bottles have a tamper-proof sealing system to preclude undetected opening, a means to affix a unique identifying number identical to that appearing on the custody and control form, and provision for initialing by the donor to affirm the identity of the specimen? (49 CFR Part 40.23 (b)(2))

FIGURE 1. (Cont'd)

☐ ☐ ☐ Yes No N/A

2.3.3 Do shipping containers used for specimens and chain of custody paperwork provide for sealing and initialing to preclude undetected tampering? Do split specimens and associated paperwork utilize a shipping or storage container meeting the same requirements? (49 CFR Part 40.23 (c))

2.4 SPECIMEN COLLECTION SITES, EQUIPMENT AND SECURITY

☐ ☐ ☐ Yes No N/A

2.4.1 Does the employer drug testing program have one or more designated collection sites which have all the necessary personnel, materials, equipment, facilities and supervision to provide for the collection, security, temporary storage and shipping of urine specimens to a testing laboratory? (Contracts for collection site services shall provide for unannounced inspections by the employer or the FAA.) (49 CFR Part 40.25(a)(1), 49 CFR Part 40.29(l))

2.4.2 Does a collection site have the following features?

☐ ☐ ☐ Yes No N/A

(a) A privacy enclosure for urination

☐ ☐ ☐ Yes No N/A

(b) A toilet for completion of urination unless a single-use collection container is of sufficient size to contain the entire void

☐ ☐ ☐ Yes No N/A

(c) A suitable clean surface for writing

FIGURE 1. (Cont'd)

Yes No N/A

(d) A source of water for hand washing, which, if practicable, should be external to the privacy enclosure.

Yes No N/A

(e) Blueing agents in toilet tanks to preclude diluting of the specimen. (49 CFR Part 40.25 (a)(2) and (f)(1))

2.4.3 Is the collection site secured as follows?

Yes No N/A

(a) A dedicated facility shall be secured at all times.

Yes No N/A

(b) That portion of a non-dedicated facility (public rest room or hospital examining room) used for testing may be secured during drug testing by visually inspecting the privacy enclosure, assuring that undetected access (e.g., through a rear door) is prevented, and posting the facility against unauthorized access. (49 CFR Part 40.25 (b)(1) and (2))

Yes No N/A

2.4.4 Is the security of the collection materials within the collection site maintained at all times? (49 CFR Part 40.25 (b)(2))

FIGURE 1. (Cont'd)

2.5 SPECIMEN COLLECTION PROCEDURES

☐ ☐ ☐ Yes No N/A

2.5.1 Upon arrival of a donor at the collection site, does the collector positively identify the individual (by photo-identification or identification by the employer's representative) and not proceed with collection unless the person is positively identified? If the donor does not arrive at the assigned time, does the collector contact the appropriate authority to obtain guidance on the action to be taken? If the donor requests, does the collector show appropriate identification? (49 CFR Part 40.25 (f)(2) and (3))

☐ ☐ ☐ Yes No N/A

2.5.2 Does the collector ask the individual to remove any unnecessary outer garments that could conceal items for use in adulterating a specimen and ensure that personal items such as purses and briefcases remain with outer garments? If requested, does the collector furnish a receipt for these articles and is the donor allowed to keep his or her wallet? (49 CFR Part 40.25 (f)(4))

☐ ☐ ☐ Yes No N/A

2.5.3 In order to avoid confusion and maintain specimen integrity, does the collector have only one donor under his/her supervision at one time until the collection process is completed (i.e., specimen has been collected, the urine bottle has been sealed and initialed, the custody and control form has been completed and the donor has departed), or in the case of an employee unable to provide a complete sample, until the employee has entered a waiting area? (49 CFR Part 40.25 (d))

☐ ☐ ☐ Yes No N/A

2.5.4 After identification, is the donor instructed to wash and dry his/her hands and required to remain in the presence of the collector (with no access to water, soap or other adulterating agents) until entering the privacy enclosure to provide the specimen? (49 CFR Part 40.25 (f)(5) and (6))

FIGURE 1. (Cont'd)

☐ ☐ ☐ Yes No N/A

2.5.5 Is the donor provided with a single-use specimen container and/or bottle and does the donor then enter the privacy enclosure or stall to provide the specimen? To the maximum extent possible, do collection site personnel keep the individual's specimen bottle within sight before and after the individual has urinated? (49 CFR Part 40.25 (f)(7)) (49 CFR Part 40.25 (g))

☐ ☐ ☐ Yes No N/A

2.5.6 Are only authorized personnel permitted in any area of the designated collection site where urine specimens are collected or stored? (49 CFR Part 40.25 (d))

☐ ☐ ☐ Yes No N/A

2.5.7 In exceptional cases where blueing agent is not available for the collection site toilet, does the collection site person instruct the individual not to flush the toilet until the specimen is delivered to the collection site person? (49 CFR Part 40.25 (f)(9))

2.5.8 Upon receipt of the specimen does the collector take the following initial actions?

☐ ☐ ☐ Yes No N/A

(a) Determines that the specimen quantity is at least 60 milliliters. (49 CFR Part 40.25 (f)(10)(i))

FIGURE 1. (Cont'd)

☐ ☐ ☐
Yes No N/A

(b) Using a device that accurately measures the temperature and does not contaminate the specimen, determines within 4 minutes that the temperature is within the range of 32.5° - 37.7°C/90.5° - 99.8°F. If so requested by the donor, does the collector take the donor's oral temperature to provide evidence as to why the specimen may have been outside the allowable range? (49 CFR Part 40.25 (f)(12) and (13))

☐ ☐ ☐
Yes No N/A

(c) Inspects the specimen to determine its color and for any signs of contaminants, noting any unusual findings on the custody and control form. (49 CFR Part 40.25 (f)(14))

2.5.9 Whenever there is reason to believe that a specimen has been altered or substituted, is such a specimen forwarded to the laboratory for testing and a second specimen obtained as soon as possible under the direct observation of a same-gender collection site person? (49 CFR Part 40.25 (f)(15) and (16)) Is an observed specimen collection conducted under the following circumstances: (49 CFR Part 40.25 (f)(16))

☐ ☐ ☐
Yes No N/A

(a) The employee has presented a urine specimen that falls outside the normal temperature range (32.5° - 37.7°C/90.5° - 99.8°F) and declines to provide a measure of oral body temperature or the oral body temperature varies by more than 1°C/1.8°F from the specimen temperature. (49 CFR Part 40.25 (e)(2)(i)(A) and (B))

☐ ☐ ☐
Yes No N/A

(b) The collection site person observes conduct clearly and unequivocally indicating an attempt to substitute or adulterate the sample (e.g., substitute urine in plain view, blue dye in specimen presented, etc.). (49 CFR Part 40.25 (e)(2)(iii))

FIGURE 1. (Cont'd)

Yes No N/A

2.5.10 Is any decision by a collection site person to obtain a specimen under the direct observation of a same gender collection site person reviewed and concurred upon by a higher-level supervisor of the collection site person or a designated employer representative? (49 CFR Part 40.25 (e)(3))

2.5.11 Do procedures for collecting urine specimens allow the donor privacy unless there is a particular reason to believe that the individual may alter or substitute his/her specimen, and are the following used as the only grounds constituting a reason to believe the individual may alter or substitute the specimen and an observed collection must be taken?

Yes No N/A

(a) The employee has presented a specimen that falls outside the normal temperature range (32.5° - 37.7°C/90.5° - 99.8°F) and either declines to provide measurement of oral body temperature or provides an oral body temperature that varies by more than 1°C/1.8°F from the temperature of the specimen. (49 CFR Part 40.25 (e)(2)(i)(A) and (B))

Yes No N/A

(b) The collection site person observes conduct clearly and unequivocally indicating an attempt to adulterate or substitute the sample. (49 CFR Part 40.25 (E)(2)(iii))

An observed collection may be taken if:

Yes No N/A

(a) The last urine specimen provided by the donor was determined by the laboratory to have a specific gravity of less than 1.003 and a creatinine concentration below 0.2 g/l. (49 CFR Part 40.25 (e)(2)(ii))

FIGURE 1. (Cont'd)

☐ ☐ ☐
Yes No N/A

(b) The donor has previously been determined to have used a controlled substance without medical authorization and the particular test was being conducted under a DOT agency regulation providing for return-to-duty testing. (49 CFR Part 40.25 (e)(2)(iv))

2.5.12 Are any unusual circumstances observed during the collection noted on the chain of custody and control form under the following circumstances?

☐ ☐ ☐
Yes No N/A

(a) The temperature is outside the range of 32.5° - 37.7°C/90.5° - 99.8°F. (49 CFR Part 40.25 (f)(13))

☐ ☐ ☐
Yes No N/A

(b) There is visual indication of contamination. (49 CFR Part 40.25 (f)(14))

☐ ☐ ☐
Yes No N/A

(c) There is unusual behavior or appearance on the part of the donor. (49 CFR Part 40.25 (f)(8))

☐ ☐ ☐
Yes No N/A

(d) The employee refuses to cooperate with the collection process and the employer's representative is contacted. (49 CFR Part 40.25 (i))

FIGURE 1. (Cont'd)

2.5.13 If the donor is unable to provide a specimen of at least 60 milliliters, does the collector direct the person to drink fluids and, after a reasonable time, again attempt to provide a complete sample in a fresh specimen container? Is the original specimen discarded (49 CFR Part 40.25 (f)(10)(i)) and, if the employee is still unable to provide a complete specimen, are the following applied?

☐ ☐ ☐ (a) For post-accident or reasonable cause collections, the employee consumes fluids and remains at the collection site until a complete specimen is collected or until 8 hours have elapsed since the beginning of the collection process. (49 CFR Part 40.25 (f)(10)(i)(A))
Yes No N/A

☐ ☐ ☐ (b) For preemployment, random, periodic or other test not for cause, the employee is requested to remain (for up to 8 hours) or is released for a subsequent collection at a later time. (49 CFR Part 40.25 (f)(10)(i)(B))
Yes No N/A

☐ ☐ ☐ (c) If the employee cannot provide a complete specimen within the 8-hour period or at a subsequent collection, the employer's MRO refers the individual for medical evaluation to determine if the inability to provide the specimen is genuine or constitutes refusal to provide a specimen and the MRO reports his or her conclusion to the employer in writing. (In preemployment testing, if the employer does not wish to hire the applicant, the MRO is not required to make such a referral.) (49 CFR Part 40.25 (f)(10)(i)(C))
Yes No N/A

FIGURE 1. (Cont'd)

2.5.14 If the employer uses a "split sample" method of collection, are the following methods used?

☐ ☐ ☐ Yes No N/A

(a) After specimen collection and temperature reading, the collector pours the specimen into two specimen bottles in the presence of the donor.

☐ ☐ ☐ Yes No N/A

(b) The first bottle is used for the DOT-mandated test and must contain 60 ml of urine regardless of the amount of urine remaining for the second bottle.

☐ ☐ ☐ Yes No N/A

(c) Up to 60 ml of the remaining specimen is poured into the second container and placed in secured refrigerated storage. If the first specimen is confirmed positive, the donor may request the MRO to direct that the second specimen be sent to a DHHS-certified laboratory for testing if the request is made within 72 hours after notification of the confirmed positive.

☐ ☐ ☐ Yes No N/A

(d) In cases where a second test of a split sample specimen is made, actions required by DOT regulations as a result of the first positive test (e.g., removal from performing a safety-sensitive function) are not delayed pending the result of the second test. (49 CFR Part 40.25 (f)(10)(ii))

FIGURE 1. (Cont'd)

2.5.15 Are the collector and donor both present and is the specimen in view of both the collector and donor during sealing, identification and labeling of the specimen container, and is the custody and control form completed as indicated below? (49 CFR Part 40.25 (f)(18))

☐ ☐ ☐ Yes No N/A

(a) The collector securely places on the bottle an identification label which contains the date, the number and any other identifying information provided or required by the employer. If separate from the label, the tamper-proof seal is also applied. (49 CFR Part 40.25 (f)(19))

☐ ☐ ☐ Yes No N/A

(b) The donor initials the identification label on the specimen bottle for the purpose of certifying that it is the specimen collected from him or her. (49 CFR Part 40.25 (f)(20))

☐ ☐ ☐ Yes No N/A

(c) The collector enters on the custody and control form all information identifying the specimen and signs the form certifying that collection was accomplished in accordance with Federal requirements. (49 CFR Part 40.25 (f)(21))

☐ ☐ ☐ Yes No N/A

(d) The donor is asked to read and sign a statement on the custody and control form certifying that the specimen identified as having been collected from him or her is in fact the specimen he or she provided. (49 CFR Part 40.24 (f)(22)(i))

FIGURE 1. (Cont'd)

Yes No N/A

(e) When required by the collection site (other than an employer site) or by the laboratory, the employee may be required to sign a consent or release form authorizing the collection of the specimen, analysis of the specimen for designated controlled substances, and release of the results to the employer. The employee is not required to waive liability with respect to negligence on the part of any person participating in the collection, handling or analysis of the specimen or to indemnify any person for the negligence of others. (49 CFR Part 40.25 (f)(22)(ii))

Yes No N/A

(f) Only the collection site person handles specimens prior to their securement in the mailing container, or monitors or observes specimen collection. (49 CFR Part 40.25 (d))

2.5.16 Is the following information completed entirely and legibly by the collector on all parts of the form for each specimen collected?

Yes No N/A

(a) The donor's employee identification or social security number. (49 CFR Part 40.23 (a)(1)(ii))

Yes No N/A

(b) The employer's name, address and identification number unless it is pre-printed. (49 CFR Part 40.23 (a)(1)(iii))

Yes No N/A

(c) The MRO's name and address. (49 CFR Part 40.23 (a)(1)(iv))

FIGURE 1. (Cont'd)

Yes No N/A

(d) The drugs for which testing is to be performed, unless the list is pre-printed. (49 CFR Part 40.23 (a)(1)(v))

Yes No N/A

(e) The reason for testing (preemployment, random, etc.). (49 CFR Part 40.23 (a)(1)(vi))

Yes No N/A

(f) The time elapsed between when the donor finished voiding the specimen and when the temperature reading was taken (must be less than 4 minutes) and whether the temperature was within the required range (32.5° - 37.7°C/90.5° - 99.8°F). (49 CFR Part 40.23 (a)(1)(vii))

Yes No N/A

(g) The actual temperature of the specimen, if not within the required range. (49 CFR Part 40.23 (a)(1)(vii))

Yes No N/A

(h) The chain of custody block for any transfer of the specimen at the collection site. (49 CFR Part 40.23 (a)(1)(viii))

Yes No N/A

(i) The collector's name, date of collection, collection site location, remarks concerning unusual collection circumstances and whether a split sample was taken. (49 CFR Part 40.23 (a)(1)(ix))

FIGURE 1. (Cont'd)

Yes No N/A

(j) The collector's signature with date following the certification statement. (49 CFR Part 40.23 (a)(1)(ix))

Yes No N/A

2.5.17 Does the collector complete the chain of custody portion of the custody and control form to indicate receipt of the specimen from the donor and certify proper completion of the collection? If the specimen is not immediately prepared for shipment, is it appropriately safeguarded during temporary storage? (49 CFR Part 40.25 (f)(23) and (24))

Yes No N/A

2.5.18 Are specimens placed in shipping containers designed to minimize the possibility of damage during shipment (e.g., specimen boxes and/or padded mailers); and are those containers securely sealed to eliminate the possibility of undetected tampering? On the tape sealing the container, does the collector sign and enter the date specimens were sealed in the shipping containers for shipment, and does the collector ensure that the chain of custody documentation is attached or enclosed in each sealed shipping container sent to the laboratory? (49 CFR Part 40.25 (h))

2.5.19 If it is impractical to maintain continuous physical security of a collection site from the time the specimen is presented until the sealed mailer is transferred for shipment, are the following minimum procedures used?

Yes No N/A

(a) The specimen and custody documents remain under the direct control of the collection site person from delivery to their being sealed in the mailer. (49 CFR Part 40.25 (b)(3)) and (49 CFR Part 40.25 (f)(25)(ii))

FIGURE 1. (Cont'd)

☐ ☐ ☐
Yes No N/A

(b) The mailer is immediately mailed, maintained in secure storage, or remains, until mailed, under the personal control of the collection site person. (49 CFR Part 40.25 (b)(3))

☐ ☐ ☐
Yes No N/A

2.5.20 If it becomes necessary for the collection site person to leave the collection site in the interval between presentation of the specimen and securing of a sample, is the collection nullified and, at the election of the employer, a new collection conducted? (49 CFR Part 40.25 (f)(25)(ii))

Appendix 4. INSPECTION PROCEDURES FOR MEDICAL REVIEW OFFICER ACTIVITIES

1. OBJECTIVE. The objective is to evaluate the performance of the Medical Review Officer (MRO). The MRO performs the final review of a laboratory drug test result and determines whether a positive result indicates prohibited drug use by the tested employee.

Applicable DOT regulations and corresponding Inspection Elements are listed below.

Applicability	Regulatory Reference	Related Inspection Elements
• Qualifications	49 CFR Part 40.33 (b)	3.1
• Responsibilities	49 CFR Part 40.33 (a,c-g)	3.2
• Laboratory Reports	49 CFR Part 40.29 (g)	3.3
• Determinations	49 CFR Part 40.33 (c,f,g,h) 14 CFR Part 121, Appendix I,VII.,C.	3.4

2. OVERVIEW. An essential part of the drug testing program is the final review of the laboratory drug test result prior to determining whether a positive result indicates prohibited drug use by the tested employee. The MRO must be a licensed physician who is knowledgeable in the medical use of prescription drugs and the pharmacology and toxicology of prohibited drugs. The primary responsibility of the MRO is to review and interpret positive test results obtained through the employer's drug testing program. A positive test result does not automatically identify an individual as an illegal drug user. The MRO must evaluate the alternative medical explanations that could account for a positive test result.

3. GENERAL APPROACH. The evaluation of the Medical Review Officer should be conducted at the MRO's facility and consist of interviews with the MRO and his/her staff, review of procedures and protocols, and inspection of records. These activities should focus on:

(1) A verification of the qualifications of the MRO and his/her staff

(2) A thorough review of the MRO's written protocol for evaluating test results

(3) An inquiry into the MRO's understanding of the collection, analysis, and reporting processes

(4) A physical inspection of the records and reports, and a check of the recordkeeping system

(5) A review of documentation sent to the Federal Air Surgeon concerning probable drug dependence for Part 67 certificate holders

4. INSPECTION ACTIVITIES. Prior to conducting the actual on-site inspection, the inspector should talk with the employer to determine whether any problems have been encountered with the MRO's performance. Employee complaints, delays in contacting employees to discuss test results, improper reporting of results, or unauthorized disclosure of sensitive information should be considered in preparing to inspect the MRO's facility. Any problems or inaccuracies should receive special attention during the on-site inspection.

During the on-site inspection (or telephone interview, if an on-site inspection is not practicable), the inspector should first introduce him/herself and explain to the MRO or the MRO's staff the nature of the inspection activity and the reason for the inspection. The inspector should assure the MRO and staff that all employee test records will be treated as strictly confidential in accordance with DOT regulations. For a no-notice inspection, the MRO and/or staff should be permitted to contact their supervisors and the employer's representative to verify the authority of the inspection personnel prior to proceeding with the inspection activity.

It is generally useful to begin the inspection activity by reviewing the areas indicated in Items 1 through 5 listed in Section 3.0 prior to beginning the actual record review process itself. This will familiarize the inspector with the knowledge of the MRO and his/her staff and put them more at ease.

Throughout the inspection process, the inspector should refer to the Checklist of Inspection Elements to assure that inspected items and procedures comply with regulatory requirements. The Checklist of Inspection Elements for this topic is found in Figure 1. The Inspection Elements are organized in a way that promotes logical examination, beginning with reviewing the MRO and staff's qualifications, continuing with their responsibilities to accurately review and interpret the testing results, and concluding with the processes used to make the final determinations of whether a test result is verified positive or negative.

While reviewing the MRO's records, any test specimens which were determined to be negative as a result of scientifically insufficient data, or on the basis of another medical explanation, should be looked at very carefully.

It is possible for the MRO to be an employee of, or affiliated with, the laboratory conducting the urine testing. If the MRO is connected with the laboratory, particular attention should be given to establishing that a specific chain of command exists so that the MRO is not influenced by the laboratory when making his/her determinations on the validity of testing results.

Particular care should be taken during the inspection to determine the adequacy of the MRO's procedures for contacting employees to discuss their test results. The MRO should be contacting the employees promptly (suggested no more than 24 hours) after he/she receives the testing results from the laboratory. In addition, detailed records should be kept documenting all attempts by the MRO or designated staff to contact the employees. If there are any instances of an MRO making a determination of a positive drug test without a consultation with the affected employee, these records should be evaluated thoroughly to determine that the procedures followed in making this determination were consistent with the regulatory requirements.

Both noteworthy and deficient observations should be identified in writing in the Checklist of Inspection Elements for MRO Activities as they are observed. This checklist is included at Attachment 1 to this appendix. Clarification of an observation with the MRO or his/her staff may be solicited as needed to verify an apparent item of non-compliance, but identifying an observation as an item of non-compliance to the MRO or employer should await completion of all inspection activity, since additional information may be revealed later in the inspection which modifies or contradicts an apparent observation.

In some cases, the MRO or his/her staff may indicate that they have experienced difficulties beyond their control. This might include inaccurate documentation from the laboratory, broken chains of custody, problems with contacting employees, or unreasonable demands from the laboratory or employer. In such cases, it may be necessary to verify these contentions with these entities. If the difficulty lies in an area being inspected by another inspector, coordination may be needed to resolve the issue and/or to assure that any observation is reported under the topic area where the responsibility lies.

5. REVIEW OF RESULTS. Informal meetings should be held each day at the conclusion of inspection activity to review the information gathered and, if necessary, to resolve any differences between the inspectors' understanding of the facts.

At the conclusion of the on-site inspection, all observations should be reviewed verbally with the MRO and, when practical, with the employer representative. Any possible sanctions which may result from items of non-compliance should not be discussed, since this determination must be reviewed and approved by headquarters.

6. REPORT WRITING. The individual inspector(s) assigned responsibility for inspecting the topic of Medical Review Officer Activities is responsible for completing the Checklist of Inspection Elements for Medical Review Officer Activities in Figure 1. Items of non-compliance should be identified as statements of fact based on observations made at the time of the inspection and generally will correlate directly to individual Inspection Elements from the Checklist. Thus, the report input represents the current status of the program and not what the inspected entity intends to do or correct in the future. Where appropriate, future plans for corrective action may be noted; however, all items of non-compliance will be noted as statements of fact. In addition to deficiencies, noteworthy practices should be identified for future dissemination to the industry. In support of individual observations, a brief analysis may be warranted to describe relationships to, and impact on, overall program performance. When an analysis is deemed necessary, it should follow the observation to which it relates. Report input will be provided to the inspection team leader at the daily meeting after the inspection process terminates.

FIGURE 1. CHECKLIST OF INSPECTION ELEMENTS FOR MEDICAL REVIEW OFFICER ACTIVITIES

3.1 QUALIFICATIONS

☐ Yes ☐ No ☐ N/A 3.1.1 Does the employer retain the services of an MRO who is a licensed physician with knowledge of substance abuse disorders? (49 CFR Part 40.33 (b)(1)) (14 CFR Part 121, Appendix I, VII., A.)

☐ Yes ☐ No ☐ N/A 3.1.2 Is the MRO currently an employee of a transportation employer or a private physician retained for this purpose? (49 CFR Part 40.33 (b))

☐ Yes ☐ No ☐ N/A 3.1.3 If the MRO is an employee of the laboratory conducting the drug test, has the laboratory established a clear separation of functions to prevent any appearance of a conflict of interest, including assuring that the MRO has no responsibility for, and is not supervised by or the supervisor of, any persons who have responsibility for the drug testing or quality control operations of the laboratory? (49 CFR Part 40.33(b)(2))

3.2 RESPONSIBILITIES.

☐ Yes ☐ No ☐ N/A 3.2.1 Does the MRO review and interpret confirmed positive test results obtained through the employer's testing program before the results are reported to the employer and summarized for the FAA? Does the report to the employer include whether the test was positive or negative and include the drugs for which the test was positive (identification of drugs is optional)? Does the report not include quantitation of test results except in the case of a grievance or lawsuit? In the case of negative test results, are the MRO's responsibilities purely administrative? (14 CFR Part 121, Appendix I, VII., B.,(1)), (49 CFR Part 40.29(g)(3)), and (49 CFR Part 40.33 (a)(2))

FIGURE 1. (Cont'd)

☐ ☐ ☐ Yes No N/A

3.2.2 Does the MRO only consider the results of urine samples that are obtained or processed in accordance with 49 CFR Part 40? (49 CFR Part 40.33 (b)(3))

☐ ☐ ☐ Yes No N/A

3.2.3 Does the MRO notify an employee of a confirmed positive test result within a reasonable time? (14 CFR Part 121, Appendix I, VII., B.,(2)) and (49 CFR Part 40.33 (c))

3.2.4 Does the MRO review and interpret each confirmed positive test result in order to determine whether there is an alternative medical explanation for the confirmed positive test result? Does the MRO perform the following functions as part of the review of a confirmed positive test result?

☐ ☐ ☐ Yes No N/A

(a) Provides an opportunity for the employee to discuss a positive test result with the MRO

☐ ☐ ☐ Yes No N/A

(b) Reviews the employee's medical history and any relevant biomedical factors

☐ ☐ ☐ Yes No N/A

(c) Reviews all medical records made available by the employee to determine whether a confirmed positive test is due to legally prescribed medication

☐ ☐ ☐ Yes No N/A

(d) Verifies that the laboratory report and assessment are correct. The MRO is authorized to request that the original specimen be reanalyzed to determine the accuracy of the reported test result. (49 CFR Part 40.33 (b) and (c)) and (14 CFR Part 121, Appendix I, VII., B., (3)(a) through (d))

FIGURE 1. (Cont'd)

☐ ☐ ☐ Yes No N/A

3.2.5 Does the MRO contact the tested individual directly, on a confidential basis in positive test result cases, to determine whether the employee wishes to discuss the test result? (A staff person under the MRO's supervision may make the initial contact with an employee whose specimen has been confirmed positive, and a medically licensed or certified staff person may gather information from the employee.) (49 CFR Part 40.33(c)(1) and (2))

☐ ☐ ☐ Yes No N/A

3.2.6 After the MRO makes all reasonable efforts to contact the individual and is unable to do so, does he/she contact a designated management official who directs the individual to contact the MRO as soon as possible? (49 CFR Part 40.33 (c)(3))

3.2.7 Does the MRO talk directly with the employee before verifying a test as positive, except for the following circumstances?

☐ ☐ ☐ Yes No N/A

(a) The employee expressly declines the opportunity to discuss the test

☐ ☐ ☐ Yes No N/A

(b) The designated employer representative has successfully made and documented a contact with the employee directing him/her to contact the MRO and more than five days have passed since the date the employee was successfully contacted by the designated employer representative

☐ ☐ ☐ Yes No N/A

(c) Other circumstances provided for by FAA drug testing regulations. (49 CFR Part 40.33 (c)(5)(i) through (iii))

FIGURE 1. (Cont'd)

☐ ☐ ☐ Yes No N/A

3.2.8 If a test is verified positive under the circumstances specified in 3.2.7 (b), is the employee allowed to present the MRO information documenting that serious illness, injury or other circumstances unavoidably prevented the employee from contacting the MRO within five days? (In this case, the MRO may reopen the verification, allowing the employee to present information concerning a legitimate explanation for the confirmed positive test.) If the MRO concludes that there is a legitimate explanation, does the MRO declare the test to be negative? (49 CFR Part 40.33 (c)(6))

☐ ☐ ☐ Yes No N/A

3.2.9 Is only the MRO authorized to order a reanalysis of the original sample should any question arise as to the accuracy or validity of a positive test result? Are such reanalyses only performed at laboratories certified by DHHS? (49 CFR Part 40.33(e))

☐ ☐ ☐ Yes No N/A

3.2.10 Does the MRO request a reanalysis of the specimen producing the positive test result if the tested individual submits a written request to the MRO no later than 60 days after receipt of notification of a confirmed positive test result? (Each individual is allowed only one such request per positive test result.) (14 CFR Part 121, Appendix I, VI., C.)

☐ ☐ ☐ Yes No N/A

3.2.11 If a retest is negative, does the MRO cancel the test? (49 CFR Part 40.33 (e))

☐ ☐ ☐ Yes No N/A

3.2.12 Does the MRO authorize analysis of a split sample, if requested to do so by the employee within 72 hours of the employee's having received actual notice of the confirmed positive test? (49 CFR Part 40.25(f)(10)(ii)(F))

FIGURE 1. (Cont'd)

☐ Yes ☐ No ☐ N/A

3.2.13 In cases where a split second test is performed due to a positive first sample test and the result of the second test is negative, does the MRO cancel the test? (49 CFR Part 40.25(f)(10)(ii)(H))

☐ Yes ☐ No ☐ N/A

3.2.14 Before the MRO verifies a confirmed positive result for opiates, does he or she determine that there is clinical evidence, in addition to the urine test, of unauthorized use of any opium, opiate or opium derivative (unless GC/MS confirmation testing for opiates confirms the presence of 6-monoacetylmorphine)? (49 CFR Part 40.33(d))

☐ Yes ☐ No ☐ N/A

3.2.15 Does the MRO ensure that an individual or employee is tested in accordance with the procedures in 14 CFR Part 121 and 49 CFR Part 40, if the person failed or refused a drug test, before the individual is hired or the employee returns to duty in a covered position? (14 CFR Part 121, Appendix I, VII., B.,(6))

☐ Yes ☐ No ☐ N/A

3.2.16 Does the MRO determine a schedule of unannounced testing not exceeding 60 months for an employee who has been hired or who has returned to duty in a covered position after the employee has failed a drug test conducted in accordance with 14 CFR Part 121 or has refused to submit to a drug test? (14 CFR Part 121, Appendix I, VII., B.,(7))

FIGURE 1. (Contd')

3.3 LABORATORY REPORTS

☐ ☐ ☐ Yes No N/A

3.3.1 Before any test results are sent to the MRO, are the results reviewed and the test certified as an accurate report by the responsible individual? Does each report identify the drugs/metabolites tested for, whether positive or negative, the specimen number assigned by the employer collection site and the drug testing laboratory specimen identification number? (49 CFR Part 40.29 (g)(1))

☐ ☐ ☐ Yes No N/A

3.3.2 Does the laboratory report test results to the employer's MRO within an average of 5 working days after receipt of the specimen by the laboratory? (49 CFR Part 40.29 (g)(1))

☐ ☐ ☐ Yes No N/A

3.3.3 Are only specimens that test positive on both the initial test and the confirmatory test reported by the laboratory as positive for a specific drug? Does the laboratory report all other tests as negative? (49 CFR Part 40.29 (g)(2))

☐ ☐ ☐ Yes No N/A

3.3.4 Upon request by the employer's MRO, does the laboratory provide the MRO with quantitation of individual test results? (49 CFR Part 40.29 (g)(3))

☐ ☐ ☐ Yes No N/A

3.3.5 Does the laboratory provide test results to the MRO to ensure confidentiality of the information, using such means as teleprinters, facsimile or computers, if they are secure, and avoiding use of the telephone? (49 CFR Part 40.29 (g)(4))

FIGURE 1. (Cont'd)

☐☐☐ Yes No N/A

3.3.6 Does the laboratory send the MRO only an original or certified copy of the drug testing custody and control form? For positive tests, is the report signed (after the required certification block) by the individual responsible for day-to-day management of the drug testing laboratory or the individual responsible for attesting to the validity of the test reports? Is a copy of the report attached to the control form? (49 CFR Part 40.29 (g)(5))

3.4 DETERMINATIONS

☐☐☐ Yes No N/A

3.4.1 If the MRO determines that there is a legitimate medical explanation for a confirmed positive test result that is consistent with legal drug use, does the MRO conclude that the test result is negative and report the test as a negative test result? (49 CFR Part 40.33(f)) and (14 CFR Part 121, Appendix I, VII., C.,(1))

☐☐☐ Yes No N/A

3.4.2 If the MRO determines, after appropriate review, that there is no legitimate medical explanation for the confirmed positive test result that is consistent with legal drug use, does the MRO refer the employee to the employer's rehabilitation program and/or to a personnel or administrative officer for further action and report the test as a positive test result? (49 CFR Part 40.33 (c)(7)) and (14 CFR Part 121, Appendix I, VII., C.,(2))

☐☐☐ Yes No N/A

3.4.3 Based on a review of laboratory inspection reports, quality assurance and quality control data and other drug test results, the MRO may conclude that a particular drug test result is scientifically insufficient for further action. Under these circumstances, does the MRO declare the test specimen negative for the presence of drugs or drug metabolites in an employee's system? (49 CFR Part 40.33(g)) and (14 CFR Part 121, Appendix I, VII., C.,(3))

FIGURE 1. (Cont'd)

☐ ☐ ☐ Yes No N/A

3.4.4 If the MRO determines that the test is scientifically insufficient, the MRO may request that reanalysis be performed before declaring the test result negative. Under these circumstances, is the reanalysis performed by the same laboratory or is an aliquot of the original specimen sent to an alternate DHHS-certified laboratory? If the reanalysis is negative does the MRO cancel the test? (49 CFR Part 40.33 (e) and (g))

☐ ☐ ☐ Yes No N/A

3.4.5 In the event of a scientifically insufficient test result, is the MRO allowed to request the laboratory to assist in the review by making available the individual responsible for day-to-day management of the urine drug testing laboratory or other employee who is a forensic toxicologist or who has equivalent forensic experience in urine drug testing? (49 CFR Part 40.33(g))

3.4.6 In order to recommend hiring an individual to perform a covered function, or to recommend that an employee return to duty in a covered position after failing or refusing to submit to a drug test, does the MRO take the following actions?

☐ ☐ ☐ Yes No N/A

(a) Ensure that the individual or employee is drug free based on a drug test that shows no positive evidence of the presence of a drug or a drug metabolite in the person's system

☐ ☐ ☐ Yes No N/A

(b) Ensure that the individual or employee has been evaluated by a rehabilitation program counselor for drug use or abuse

FIGURE 1. (Cont'd)

☐ ☐ ☐
Yes No N/A

(c) Ensure that the individual or employee demonstrates compliance with any conditions or requirements of a rehabilitation program in which the person participated. (14 CFR Part 121, Appendix I, VII., C.,(4) (a through c))

☐ ☐ ☐
Yes No N/A

3.4.7 In cases where an individual has failed a drug test, or refused to submit to a test, does the MRO determine, in accordance with the employer's anti-drug program, whether a recommendation for return to duty for a current employee, or a recommendation for a decision to hire an individual into a covered position, is appropriate or not? (This determination may be supported by the inclusion of a review of any rehabilitation program in which the individual or employee participated.) (14 CFR Part 121, Appendix I, VII.,B.,(5))

3.4.8 Does the MRO make the following determinations in the case of an employee or applicant who holds, or is required to hold, a medical certificate issued pursuant to 14 CFR Part 67 in order to perform a covered function?

☐ ☐ ☐
Yes No N/A

(a) The MRO reports to the Federal Air Surgeon the name of any employee who is required to hold a medical certificate issued pursuant to 14 CFR Part 67 and who fails a drug test. The MRO reports to the Federal Air Surgeon the name of any person who applies for a position that requires the person to hold a medical certificate issued pursuant to 14 CFR Part 67 and who fails a preemployment drug test. (14 CFR Part 121, Appendix I, VII, C.,(5)(c))

FIGURE 1. (Cont'd)

☐ ☐ ☐
Yes No N/A

(b) For an individual who fails a drug test, the MRO makes a determination of probable drug dependence or nondependence. If nondependence is determined, he or she may recommend that the employee return to duty in a position that requires the employee to hold a certificate issued under 14 CFR Part 67. The MRO forwards the determination of nondependence, the return-to-duty decision, and any supporting documentation to the Federal Air Surgeon for review. (14 CFR Part 121, Appendix I, VII., C.,(5)(a))

☐ ☐ ☐
Yes No N/A

(c) If the MRO makes a determination of probable drug dependence at any time, he/she reports the name of the individual, additional identifying information, the determination of probable drug dependence and any supporting documentation to the Federal Air Surgeon. The MRO does not have the authority to recommend that the employee return to duty in a position that requires the employee to hold a certificate issued under 14 CFR Part 67. (14 CFR Part 121, Appendix I, VII., C.,(5)(b))

3.4.9 Except for the following instances, does the MRO refrain from disclosing to any third party medical information provided by the individual to the MRO as a part of the testing verification process?

☐ ☐ ☐
Yes No N/A

(a) The MRO may disclose such information to the employer, the FAA or other Federal safety agency, or a physician responsible for determining the medical qualification of the employee under FAA regulations, only if:

(1) An applicable DOT regulation permits or requires such disclosure; or

(2) In the MRO's reasonable medical judgment, the information could result in the employee being determined to be medically unqualified under an applicable DOT agency rule; or

FIGURE 1. (Cont'd)

(3) In the MRO's reasonable medical judgment, in a situation in which there is no DOT agency rule establishing physical qualification standards applicable to the employee, the information indicates that continued performance by the employee of his/her safety-sensitive function could pose a significant safety risk.

☐ ☐ ☐
Yes No N/A

(b) Before obtaining medical information from the employee, the MRO informs the employee that information may be disclosed to third parties as provided in 3.4.9(a), and the names of those parties. (49 CFR Part 40.33 (h)(1)(2))

Appendix 5. INSPECTION PROCEDURES FOR EMPLOYEE ASSISTANCE PROGRAMS (EAP)

1. OBJECTIVE. The objective is to evaluate the education and training provided to employees and supervisors on the employer's drug abuse policy and the effects and consequences of prohibited drug use, and to assess the availability of information regarding community resources that offer assistance to individuals suffering from drug abuse.

Applicable DOT regulations and corresponding Inspection Elements are listed below.

Applicability	Regulatory Reference	Related Inspection Elements
• Employee Education Program	14 CFR Part 121, Appendix I, VIII., A.	4.1
• Employee & Supervisor Training Program	14 CFR Part 121, Appendix I, VIII., B.	4.2

2. OVERVIEW. Employee Assistance Programs are intended to cover a variety of issues, but primarily serve to create a proactive anti-drug program which informs employees about the effects of substance abuse and available forms of assistance and treatment. The employer benefits not only by educating employees on the effects and consequences of drug use, but also by training supervisors to recognize the signs of drug use.

3. GENERAL APPROACH. The major source of information regarding employee assistance programs is the program documentation, which should be the main focus of the on-site inspection. Activities should include:

(1) A thorough review of the written policies and procedures that establish the employee assistance program

(2) Physical inspection of the facilities to ensure the visible presence of informational material concerning drug abuse, including a community service hotline telephone number, the employer's policy on drug use in the workplace, and any information regarding available assistance and treatment programs

(3) Inspection of training records, including names of persons who received the training, the dates on which training occurred, and the information given during the course of training

(4) Review of the process by which all employees are provided with printed material concerning drug abuse for future reference

(5) Observation of the actual conduct of training and/or review of training materials to assure content addresses all regulatory requirements for employer and supervisor training

(6) Actual interviews with employees and supervisors to ascertain their general level of knowledge and understanding of their responsibilities within the anti-drug program.

4. INSPECTION ACTIVITIES. When conducting the on-site inspection, the inspector should first introduce him/herself and explain to the employer's representative(s) the nature of the inspection activity and the reason for the inspection. In the case of a no-notice inspection, on-duty personnel should be permitted to contact their supervisors and the employer representatives to verify the authority of the inspection personnel prior to proceeding with the inspection.

Throughout the inspection process, the Checklist of Inspection Elements should be referred to in order to assure that inspected items and procedures comply with regulatory requirements. The Checklist for this topic is found in Figure 1. Both noteworthy and deficient observations should be identified in writing on the Checklist of Inspection Elements, as they are observed. Clarification of an observation may be solicited to verify an apparent item of non-compliance, but identifying an observation as an item of non-compliance to the employer should await completion of all inspection activity, since additional information may be revealed later in the inspection which modifies or contradicts an apparent observation.

In addition to evaluating the adequacy of individual training records and displays of information by the employer, the inspector should attempt to evaluate the adequacy, in terms of content and quality, of the training. This can be done, in part, by reviewing training lesson plans and handout materials and, when possible, observing or participating in an actual training session. In addition, the inspector should interview several employees and supervisors to ascertain their perceptions of the training and determine the degree of information retention.

Whenever possible, observations should be based on physical inspection and observable evidence. Verbal descriptions or assertions by staff members should not be relied on as proof of compliance with regulatory requirements.

5. REVIEW OF RESULTS. Informal meetings should be held each day at the conclusion of inspection activity to review the information gathered and, if necessary, to resolve any differences between the inspectors' understanding of the facts.

At the conclusion of the on-site inspection, all observations should be reviewed verbally with the employer's representative to allow for clarifications and provide the employer with an understanding of the results of the inspection. Any possible sanctions which may result from items of non-compliance should not be discussed, since this determination must be reviewed and approved by headquarters.

6. REPORT WRITING. The individual inspector(s) assigned responsibility for inspecting the topic of Employee Assistance Programs is responsible for completing the Checklist of Inspection Elements for Employee Assistance Programs found in Figure 1. Items of non-compliance should be noted as statements of fact based on observations made at the time of the inspection and generally will correlate directly to individual Inspection Elements from the Checklist. Thus, the report input represents the current status of the program and not what the inspected entity intends to do or correct in the future. Where appropriate, future plans for corrective action may be noted; however, all items of non-compliance will be noted as statements of fact. In addition to deficiencies, noteworthy practices should be identified for future dissemination to the industry. In support of individual observations, a brief analysis of each may be warranted to describe its relationship to, and impact on, overall program performance. When an analysis is deemed necessary, it should follow the observation to which it relates. Report input will be provided to the inspection team leader at the daily meeting after the inspection process terminates.

FIGURE 1. CHECKLIST OF INSPECTION ELEMENTS FOR EMPLOYEE ASSISTANCE PROGRAMS (EAP)

4.1 EMPLOYEE EDUCATION PROGRAM

4.1.1 Are the following materials displayed and distributed to all covered employees?

☐ ☐ ☐ Yes No N/A

(a) Informational materials concerning drug abuse

☐ ☐ ☐ Yes No N/A

(b) A community service hot-line telephone number for employee assistance

☐ ☐ ☐ Yes No N/A

(c) The employer's policy regarding drug use in the work place. (14 CFR Part 121, Appendix I, VIII., A.)

4.2 EMPLOYEE AND SUPERVISOR TRAINING PROGRAM

4.2.1 Does training for all employees in covered positions include the following items?

☐ ☐ ☐ Yes No N/A

(a) Effects and consequences of drug use on personal health, safety and work environment

☐ ☐ ☐ Yes No N/A

(b) Manifestations and behavioral cues that may indicate drug use and abuse

FIGURE 1. (Cont'd)

Yes No N/A

(c) Documentation of training, including names of persons receiving the training, the dates they received training, and what the training consisted of. (14 CFR Part 121, Appendix I, VIII., B.)

Yes No N/A

4.2.2 Have all supervisors who are in a position to require testing of employees for reasonable cause received a minimum of 60 minutes of initial training on the specific, contemporaneous physical, behavioral and performance indicators of probable drug use, in addition to the general employee education? (14 CFR Part 121, Appendix I, VIII., B.)

Yes No N/A

4.2.3 Do all supervisors who are in a position to require testing of employees for reasonable cause participate in a reasonable recurrent training program covering the subjects listed in 4.2.2? (14 CFR Part 121, Appendix I, VIII., B.)

Appendix 6. INSPECTION PROCEDURES FOR RECORDKEEPING AND REPORTING

1. OBJECTIVE. The objective is to assess the employer's compliance with the recordkeeping and reporting requirements of the FAA's Anti-Drug Program. This entails reviewing the procedures and the documentation for establishing, maintaining, and retaining program records. Emphasis should be placed on assessing confidentiality as well as adherence to Federal reporting requirements.

The applicable DOT regulations and the corresponding Inspection Elements are listed below.

Applicability	Regulatory Reference	Related Inspection Elements
• Records Maintenance	14 CFR Part 121, Appendix I, VI., A.	5.1
• Confidentiality of Records	14 CFR Part 121, Appendix I, VI., D.	5.2
• Semiannual/Annual Reporting	14 CFR Part 121, Appendix I, X.	5.3

2. OVERVIEW. Each aviation entity involved in the anti-drug program is required to maintain records detailing its anti-drug program and to submit semiannual and annual reports to the FAA summarizing the results of that program. Adequate recordkeeping and reporting are essential elements of the program. The regulatory provisions that require an employer to submit a comprehensive anti-drug plan and summary reports of the employer's program are critical measures to provide oversight of the industry's implementation of the regulation.

3. GENERAL APPROACH. The FAA requires employers to generate and maintain records and to submit documentation to certify compliance with the FAA anti-drug rule. The task of the inspector is to verify the accuracy and completeness of that documentation. All anti-drug program records shall be maintained and managed so that they are available for inspection upon request by the FAA.

On-site inspection activities will entail assessing the procedures and documentation involved with the anti-drug program records, with focus on confidentiality and adherence to Federal reporting requirements. The inspection of recordkeeping and reporting should include the following activities:

(1) Reviewing recordkeeping and reporting policies, guidance, and procedures with particular emphasis on confidentiality (Also see Appendices A and C)

(2) Reviewing documents, records, and logbooks related to the drug testing process (Also see Appendix A)

(3) Reviewing training records, lesson plans, and course materials. (This activity shall be performed in conjunction with the EAP training inspection discussed in Appendix D)

(4) Sampling records of covered employees to verify accuracy and appropriateness of records (Also see Appendices A and C)

(5) Reviewing planned corrective actions and followup to previous inspections

(6) Determining whether the employer has met reporting requirements.

4. INSPECTION ACTIVITIES. The inspectors will review the employer's compliance with recordkeeping and reporting requirements of 49 CFR Part 40 and 14 CFR Part 61 et al. The inspectors will use the Checklist of Inspection Elements found at Attachment 1 to evaluate compliance. In cases where an exhaustive review of records is not feasible due to large numbers, appropriate sampling techniques will be employed to review up to a maximum of 200 of each type of record.

An initial review of the employer's anti-drug plan, previous inspection reports, and semiannual and annual reports, prior to the on-site assessment, will provide a foundation for understanding the employer's program. Any obvious problem areas or past deficiencies can be identified at that time. Upon arrival at the inspected employer's facility, the inspection team should be introduced and the nature of the inspection and its required activities discussed. If it is a no-notice inspection, the inspected staff must be permitted to contact their supervisors or anti-drug program manager to verify the identity and authority of the inspection team.

While the six steps in Section 3.0 offer a general overview of efforts for any inspection of an anti-drug program, they are not all-inclusive. A cross reference of all pertinent Inspection Elements should be made to ensure that all aspects of recordkeeping and reporting are covered during the inspection. A review of the recordkeeping and reporting will include:

(1) Reviewing internal policies, guidance, and procedures to determine whether they provide adequate guidance to implement the recordkeeping and reporting provisions of the regulations and provide for confidentiality

(2) Reviewing aspects of recordkeeping and reporting which ensure confidentiality, such as the location and procedures for custodial control. Access to individual records should be strictly controlled and the records should be stored in a secure location. If possible, they should not be co-located with personnel records. If specific written consent for release of information was given, it should be in the records

(3) Comparing semiannual/annual reports with employer records and laboratory and MRO reports to determine accuracy of information submitted to FAA

(4) Reviewing semiannual/annual reports to determine whether they are being submitted as required and whether their contents meet regulatory requirements as described below

Submitting reports within 45 days following the end of the specified period -

Semiannual reports
Cover January 1 through June 30, due August 15

Annual reports
Cover January 1 through December 31, due February 15

Submitting required information, including - (but not limited to)

Total number of tests
Total number of positive test results by test category
Total number of tests by function
Total number of positive test results by drug

(5) Reviewing training records, lesson plans, and course materials to determine whether all covered employees and supervisors receive training in accordance with the regulations. A full 60 minutes of initial training is required for presently employed and newly hired supervisors making reasonable cause determinations. (This area may be inspected as part of the EAP/training function described in Appendix D.)

(6) Selecting a sample of employees' names in covered positions and examining the recordkeeping system to determine whether testing and training records exist for those employees. The contents of those records will also be reviewed to determine whether the recordkeeping system is in compliance with the regulations

(7) Reviewing planned corrective actions of any previous inspection deficiencies and their followup, status, and closeout

(8) Reviewing the following documents, records, and logbooks related to the collection process:

Logbooks and certification statements retained for two years

Positive test results and rehabilitation records retained for five years

Negative test results retained for one year.

The regulatory provisions that require an employer to maintain records and submit summary reports are critical measures to provide oversight of the industry's implementation of the anti-drug program. Any requests for exemption from a requirement of the regulations should be handled in the same manner as requests for exemptions of other FAA regulations under Part 11 of the Federal Aviation Regulations, and that exemption should be documented in the employer's records.

The Inspection Elements at Attachment 1 provide the basis for assessment and should be referred to throughout the inspection process. Both noteworthy practices and deficiencies should be identified in writing as they are observed. If possible, ready references (such as a name, record number, date, or location) should be noted in the event they are required for followup review or verification. Clarification of any observation with the employer's staff may prove useful to verify the observation and prevent having to return to that particular location. Identifying an observation as an item of non-compliance to the employer should await completion of all inspection activity since additional information may be revealed later which modifies or contradicts an apparent observation.

Whenever possible, observations should be based on empirical data, physical inspection and observable evidence. Verbal descriptions or statements by employer staff should not be used as the sole basis to verify documentation processes. If no other means of verification exists, any statements pertaining to recordkeeping or reporting should be noted and confirmed through other inspector observations, if possible. Actual observation and review of documentation should always be the first choice.

If a deficiency is noted by an inspector in one area, it may become necessary to coordinate among the team members to discuss and resolve the issue and to assure any observation is reported under the applicable topic area.

5. REVIEW OF RESULTS. Informal meetings should be held each day at the conclusion of inspection activity to review the information gathered and, if necessary, to resolve any differences between the inspectors' understanding of the facts.

At the conclusion of the on-site inspection, all observations should be reviewed verbally with the employer's representative to allow for clarifications and provide the employer with an understanding of the inspection results. Any possible sanctions which may result from items of non-compliance should not be discussed, since this determination must be reviewed and approved by headquarters.

6. REPORT WRITING. The individual inspector(s) assigned responsibility for inspecting the topic of Recordkeeping and Reporting is responsible for completing the Checklist of Inspection Elements for Recordkeeping and Reporting found at Attachment 1. Items of non-compliance should be noted as statements of fact based on observations made at the time of the inspection and generally will correlate directly to individual Inspection Elements from the Checklist. Thus, the report input represents the current status of the program and not what the inspected entity intends to do or correct in the future. Where appropriate, future plans for corrective action may be noted; however, all items of non-compliance will be noted as statements of fact. In addition to deficiencies, noteworthy practices should be identified for future dissemination to the industry. In support of individual observations, a brief analysis may be warranted to describe relationships to, and impact on, overall program performance. When an analysis is deemed necessary, it should follow the observation to which it relates. Report input will be provided to the inspection team leader at the daily meeting after the inspection process terminates.

FIGURE 1. CHECKLIST OF INSPECTION ELEMENTS FOR RECORDKEEPING AND REPORTING

5.1 RECORDS MAINTENANCE

☐ ☐ ☐ Yes No N/A

5.1.1. Does the employer maintain all records related to the collection process, including all logbooks and certification statements, for 2 years? (14 CFR Part 121, Appendix I, VI., A.)

☐ ☐ ☐ Yes No N/A

5.1.2 Does the employer maintain collection process and test records of positive tests for 5 years? (14 CFR Part 121, Appendix I, VI., A.)

☐ ☐ ☐ Yes No N/A

5.1.3 Does the employer maintain collection process and test records of negative tests for 12 months? (14 CFR Part 121, Appendix I, VI., A.)

☐ ☐ ☐ Yes No N/A

5.1.4 Does the employer maintain records of employee rehabilitation for 5 years? (14 CFR Part 121, Appendix I, VI., A.)

FIGURE 1. (Cont'd)

☐ ☐ ☐
Yes No N/A

5.1.5 Does the laboratory provide the employer's official responsible for coordination of the drug testing program with a monthly statistical summary of urinalysis testing within 14 calendar days after the end of the month covered by the summary? Is this report sent by registered or certified mail and does it exclude any personal identifying information? Does the summary contain the following information?

(a) Initial Testing:

Number of specimens received
Number of specimens reported out
Number of specimens screened positive for:
- Marijuana metabolites
- Cocaine metabolites
- Opiate metabolites
- Phencyclidine
- Amphetamines

(b) Confirmatory Testing:

Number of specimens received for confirmation
Number of specimens confirmed positive for:
- Marijuana metabolites
- Cocaine metabolites
- Opiates
- Morphine, Codeine
- Phencyclidine
- Amphetamines
- Methamphetamine

(49 CFR Part 40.29 (g)(6))

FIGURE 1. (Cont'd)

☐ ☐ ☐ Yes No N/A

5.1.6 Do the monthly reports provided by the laboratory exclude data from which it is reasonably likely that information about an individual's identity can be readily inferred? If necessary, in order to prevent the disclosure of such data, does the laboratory retain a report until data are sufficiently aggregated to make such an inference unlikely? Does the laboratory inform the employer in writing any time a report is withheld for this reason?
(49 CFR Part 40.29 (g)(6))

5.1.7 Does the laboratory maintain and make available documentation of all aspects of the testing process for at least 2 years? Does the laboratory extend this 2-year period, upon written notification from the FAA or by any employer for which the laboratory provides urine drug testing services? Does the laboratory maintain documents for any specimen known to be under legal challenge for an indefinite period until notified otherwise? Does this information include the following items?

☐ ☐ ☐ Yes No N/A

(a) Personnel files on all individuals authorized to have access to specimens

☐ ☐ ☐ Yes No N/A

(b) Chain of custody documents

☐ ☐ ☐ Yes No N/A

(c) Quality assurance/quality control records

☐ ☐ ☐ Yes No N/A

(d) Procedure manuals

FIGURE 1. (Cont'd)

☐ ☐ ☐ Yes No N/A

(e) All test data (including calibration curves and any calculations used in determining test results)

☐ ☐ ☐ Yes No N/A

(f) Reports

☐ ☐ ☐ Yes No N/A

(g) Performance records on performing testing

☐ ☐ ☐ Yes No N/A

(h) Performance on certification inspections

☐ ☐ ☐ Yes No N/A

(i) Hard copies of computer-generated data.

(49 CFR Part 40.29 (m))

5.2 CONFIDENTIALITY OF RECORDS

☐ ☐ ☐ Yes No N/A

5.2.1 Is the release by the employer of an individual's drug test results and any information about an employee's rehabilitation program to any third party (other than the FAA or the National Transportation Safety Board (NTSB) permitted only with the specific, written consent of the individual? (14 CFR Part 121, Appendix I, VI., D.)

FIGURE 1. (Cont'd)

☐ ☐ ☐ Yes No N/A

5.2.2 Is information regarding an employee's drug testing result or rehabilitation released to the National Transportation Safety Board only as part of an accident investigation, or to the FAA upon request or as required by 14 CFR Part 121, Appendix I, VII., C., 5.? (14 CFR Part 121, Appendix I, VI., D.)

☐ ☐ ☐ Yes No N/A

5.2.3 Does the employer's contract with a testing laboratory require that the laboratory maintain employee test records in confidence and disclose testing information only to the tested individual; the employer; the FAA; or the decisionmaker in a lawsuit, grievance or other proceeding initiated by or on behalf of the individual and arising from a certified positive drug test? (49 CFR Part 40.35)

☐ ☐ ☐ Yes No N/A

5.2.4 Are employees who are the subject of a drug test covered under FAA regulations given access, upon written request, to any records relating to their drug test and any records relating to the results of any relevant certification, review or revocation-of-certification proceedings? (49 CFR Part 40.37)

5.3 SEMIANNUAL/ANNUAL REPORTING

☐ ☐ ☐ Yes No N/A

5.3.1 Does the employer submit to the FAA a semiannual report for the period January 1 - June 30 and an annual report for the period January 1 - December 31, not later than August 15 and February 15, respectively, summarizing the results of the drug testing program for the period? (14 CFR Part 121, Appendix I, X., A.)

FIGURE 1. (Cont'd)

5.3.2 Does each report include the following information?

☐ ☐ ☐
Yes No N/A

(a) Total number of tests performed and the total number of tests performed for each category of test (14 CFR Part 121, Appendix I, X., B., 1.)

☐ ☐ ☐
Yes No N/A

(b) Total number of positive test results by category of test; total number of positive test results by each function listed in 14 CFR Part 121, Appendix I, III.; and total number of positive test results by the type of drug identified in a positive test result (14 CFR Part 121, Appendix I, X., B., 2.)

☐ ☐ ☐
Yes No N/A

(c) Disposition of an individual who failed or refused a drug test conducted in accordance with 14 CFR Part 121, Appendix I, by each category of test (14 CFR Part 121, Appendix I, X., B., 3.)

☐ ☐ ☐
Yes No N/A

(d) A summary of any negative finding based on scientific insufficiency which does not include any personal identifying information. (49 CFR Part 40.33 (g))

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